US3292127 (Prod: Clinical Trials of Texas, Inc)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:21:43

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US3292127
Form: Participant Creation
Data signed: (b) (4) **22 Feb 2021 18:47:36**
Generated On: 09 Jun 2021 16:21:43

Participant ID	US3292127

mRNA-1273-P301 Completion Guidelines

US3292127

Folder: Screening

Form: Visit Date

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Was this visit performed?	Yes ⬤
	No ◯

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

Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Date of Birth (MMM yyyy)	(b) (6) 1945
Age	74
Age Units	YEARS
Age (Derived)	74

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) **22 Feb 2021 18:47:41**

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Date of Informed Consent *(dd MMM yyyy)*	11 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020

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

Was participant enrolled in the study?
- Yes ●
- No ○

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

If reason for screen fail is Other, specify _____

Was this participant screened previously?
- Yes ○
- No ●

If Yes, previous participant number _____

Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) **22 Feb 2021 18:47:41**

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Did the participant meet all eligibility criteria?   Yes ●

No ○

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) **22 Feb 2021 18:47:41**

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Were any significant conditions reported?   Yes ●

                                                             No ○

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) **22 Feb 2021 18:47:41**

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Condition	DECREASED VISUAL ACUITY
Start date (dd MMM yyyy)	UN UNK 1953
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 1953
Start Year (derived)	1953
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

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: Vital Signs

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	11 AUG 2020
Time of assessment *(00:00-23:59)*	13:00 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 13:00
Height *(xxx.x)*	176.3 cm
Weight *(xxx.x)*	97.9 kg
BMI *(xxx.x)*	31.49764 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) **22 Feb 2021 18:47:41**

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Was the physical examination performed?	Yes ●
	No ○

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

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **22 Feb 2021 18:47:41**

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Occupational Risk

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

Specify _____

Location and Living Circumstances Risk (check all that apply)

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **22 Feb 2021 18:47:41**

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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) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Was this visit performed?	Yes ●
	No ○

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

Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) **22 Feb 2021 18:47:41**

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What was the date of randomization? *(dd MMM yyyy)*	11 AUG 2020
What was the participant's randomization number?	185729

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) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

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) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	11 AUG 2020
Time of assessment *(00:00-23:59)*	13:00 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 13:00
Temperature *(xxx.x)*	36.6 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	69 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	160 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ⭕
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ⭕
Date of assessment *(dd MMM yyyy)*	11 AUG 2020
Time of assessment *(00:00-23:59)*	14:40 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 14:40
Temperature *(xxx.x)*	36.3 C
Route of measurement	Oral ⬤
	Axillary ⭕
	Other ⭕
If Other, specify	
Pulse *(xxx)*	74 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	187 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	99 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

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.

US3292127
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **22 Feb 2021 18:47:41**
Generated On: 09 Jun 2021 16:21:43

Was study treatment given?	Yes ●
	No ○

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

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	11 AUG 2020
What was the treatment time? *(00:00-23:59)*	14:06 (24 HR)
Treatment Date and Time (derived)	11 AUG 2020 14:06
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) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	11 AUG 2020
Collection time *(00:00-23:59)*	13:09 (24 HR)
Collection date and time (derived)	11 AUG 2020 13:09

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Collection date *(dd MMM yyyy)*			11 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:28	11 AUG 2020 13:28
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

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

Continuing Flag	1

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

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

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

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

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

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

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

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

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	11 AUG 2020 14:43
PC Open Date & Time	11 AUG 2020 14:26
PC Close Date & Time	11 AUG 2020 16:56

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.8 °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	11 AUG 2020 18:26
PC Open Date & Time	11 AUG 2020 17:51
PC Close Date & Time	12 AUG 2020 11:59

FDA-CBER-2022-1614-1665277

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 2

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	98.7 °F

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

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

PC Time Stamp	12 AUG 2020 18:35
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:21:43

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	13 AUG 2020 18:33
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

FDA-CBER-2022-1614-1665279

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 4

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

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

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

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

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

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

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

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

PC Time Stamp	14 AUG 2020 18:35
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

TIMEPOINT	**DAY 5**

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	98.4 °F

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

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

PC Time Stamp	15 AUG 2020 18:36
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

FDA-CBER-2022-1614-1665281

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Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 6

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	98.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	16 AUG 2020 18:31
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3292127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 7

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	98.3 °F

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

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

PC Time Stamp	17 AUG 2020 18:28
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE?**	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE?**	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	11 AUG 2020 14:44
PC Open Date & Time	11 AUG 2020 14:26
PC Close Date & Time	11 AUG 2020 16:56

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	11 AUG 2020 18:28
PC Open Date & Time	11 AUG 2020 17:51
PC Close Date & Time	12 AUG 2020 11:59

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	12 AUG 2020 18:36
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

TIMEPOINT	**DAY 3**
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	13 AUG 2020 18:33
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤ Does not interfere with activity ◯ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯ Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯ No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯ No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤ Does not interfere with activity ◯ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯ Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	14 AUG 2020 18:36
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	15 AUG 2020 18:37
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 6
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE?**	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE?**	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	16 AUG 2020 18:31
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	17 AUG 2020 18:28
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3292127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

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 ○

US3292127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	11 AUG 2020 14:45
PC Open Date & Time	11 AUG 2020 14:26
PC Close Date & Time	11 AUG 2020 16:56

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:21:43

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	◯

US3292127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:43

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	11 AUG 2020 18:31
PC Open Date & Time	11 AUG 2020 17:51
PC Close Date & Time	12 AUG 2020 11:59

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 2

HEADACHE

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

FATIGUE

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

MUSCLE ACHES ALL OVER BODY

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

JOINT ACHES IN SEVERAL JOINTS

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

NAUSEA/VOMITING

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

CHILLS

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

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

Yes ◯

PC Time stamp	12 AUG 2020 18:38
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

TIMEPOINT	DAY 3

HEADACHE

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

FATIGUE

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

MUSCLE ACHES ALL OVER BODY

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

JOINT ACHES IN SEVERAL JOINTS

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

NAUSEA/VOMITING

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

CHILLS

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

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

	Yes ◯
PC Time stamp	13 AUG 2020 18:34
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:21:43

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	14 AUG 2020 18:37
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:21:43

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	15 AUG 2020 18:37
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 6

HEADACHE

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

FATIGUE

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

MUSCLE ACHES ALL OVER BODY

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

JOINT ACHES IN SEVERAL JOINTS

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

NAUSEA/VOMITING

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

CHILLS

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

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

Yes ◯

PC Time stamp	16 AUG 2020 18:32
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 7

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

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

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

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

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

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

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

Yes ◯

PC Time stamp	17 AUG 2020 18:29
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3292127
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **22 Feb 2021 18:47:41**
Generated On: 09 Jun 2021 16:21:43

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*	18 AUG 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3292127
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **22 Feb 2021 18:47:41**
Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3292127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Was Contact Attempted?	Yes ⬤
	No ◯
Date of Contact or Contact Attempt *(dd MMM yyyy)*	26 AUG 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments _____

US3292127

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3292127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

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

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

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

Comments

If Contact Not Made, please provide Comments _____

US3292127

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?   Yes ●

                                                                                    No ◯

Continuing Flag   1

Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **22 Feb 2021 18:47:41**
Generated On: 09 Jun 2021 16:21:43

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	8 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	VISIT2

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	8 SEP 2020
Time of assessment *(00:00-23:59)*	11:38 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 11:38
Temperature *(xxx.x)*	36.6 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	81 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	87 mmHg
Diastolic Blood Pressure units	MMHG

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	8 SEP 2020
Time of assessment *(00:00-23:59)*	12:51 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 12:51
Temperature *(xxx.x)*	36.5 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	73 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	166 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	89 mmHg
Diastolic Blood Pressure units	MMHG

US3292127

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Was the physical examination performed? Yes ●

No ○

Date of examination *(dd MMM yyyy)* 8 SEP 2020

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

US3292127
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) 22 Feb 2021 18:47:41
Generated On: 09 Jun 2021 16:21:43

Was study treatment given?	Yes ●
	No ○

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

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	8 SEP 2020
What was the treatment time? *(00:00-23:59)*	12:21 (24 HR)
Treatment Date and Time (derived)	8 SEP 2020 12:21
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

US3292127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Was the sample collected?	Yes ●
	No ◯

Collection date *(dd MMM yyyy)*	8 SEP 2020
Collection time *(00:00-23:59)*	11:43 (24 HR)
Collection date and time (derived)	8 SEP 2020 11:43

US3292127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Collection date *(dd MMM yyyy)*			8 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:55	8 SEP 2020 11:55
Nasopharyngeal Swab 2	No		

US3292127

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?   Yes ●

                                                                                                           No ○

Continuing Flag   1

US3292127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

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

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

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

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

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

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

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

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

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

PC Time Stamp	08 SEP 2020 12:59
PC Open Date & Time	08 SEP 2020 12:41
PC Close Date & Time	08 SEP 2020 15:11

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**	
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	08 SEP 2020 16:06
PC Close Date & Time	09 SEP 2020 11:59

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	09 SEP 2020 12:48
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:21:43

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**	97.6 °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	10 SEP 2020 12:23
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	11 SEP 2020 18:30
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 5

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	98.5 °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	12 SEP 2020 12:31
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3292127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:21:43

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	13 SEP 2020 12:28
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

FDA-CBER-2022-1614-1665328

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	14 SEP 2020 13:28
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

FDA-CBER-2022-1614-1665329

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	08 SEP 2020 12:59
PC Open Date & Time	08 SEP 2020 12:41
PC Close Date & Time	08 SEP 2020 15:11

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ◯ Does not interfere with activity ◯ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯ Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE?**	Yes ◯ No ◯
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
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	08 SEP 2020 16:06
PC Close Date & Time	09 SEP 2020 11:59

FDA-CBER-2022-1614-1665331

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	09 SEP 2020 12:49
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.**	None ⬤
Please select one response below	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.**	None ⬤
Please select one response below	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	10 SEP 2020 12:24
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	11 SEP 2020 18:30
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3292127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	12 SEP 2020 12:32
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

TIMEPOINT	DAY 6

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

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

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

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

PC Time Stamp	13 SEP 2020 12:28
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 7

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

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

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

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

PC Time Stamp	14 SEP 2020 13:28
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3292127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

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 ○

US3292127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

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

PC Time stamp	08 SEP 2020 13:00
PC Open Date & Time	08 SEP 2020 12:41
PC Close Date & Time	08 SEP 2020 15:11

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:21:43

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	◯

Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:21:43

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ◯ Yes ◯
PC Time stamp	
PC Open Date & Time	08 SEP 2020 16:06
PC Close Date & Time	09 SEP 2020 11:59

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:21:43

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 ●

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:21:43

	Yes ◯
PC Time stamp	09 SEP 2020 12:49
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:21:43

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	10 SEP 2020 12:25
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:21:43

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 ●

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:21:43

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

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:21:43

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	12 SEP 2020 12:32
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 6

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

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

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

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

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

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

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

Yes ◯

PC Time stamp	13 SEP 2020 12:29
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

TIMEPOINT	DAY 7

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

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

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

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

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

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

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

Yes ◯

PC Time stamp	14 SEP 2020 13:29
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3292127
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **22 Feb 2021 18:47:41**
Generated On: 09 Jun 2021 16:21:43

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

Comments

If Contact Not Made, please provide Comments

US3292127

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?   Yes ●

                                                                                    No ○

Continuing Flag   1

US3292127
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **22 Feb 2021 18:47:41**
Generated On: 09 Jun 2021 16:21:43

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*	23 SEP 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments _____

US3292127

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?   Yes ●

                                                                                    No ◯

Continuing Flag   1

US3292127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?   Yes ●

                                                                                    No ○

Continuing Flag   1

US3292127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	6 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT3

US3292127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	6 OCT 2020
Time of assessment *(00:00-23:59)*	09:58 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 09:58
Temperature *(xxx.x)*	37.8 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	83 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	186 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	96 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3292127

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Was the physical examination performed?
Yes ⭘
No ⬤

Date of examination *(dd MMM yyyy)* _____

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

Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **22 Feb 2021 18:47:41**
Generated On: 09 Jun 2021 16:21:43

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	6 OCT 2020
Collection time *(00:00-23:59)*	10:10 (24 HR)
Collection date and time (derived)	6 OCT 2020 10:10

US3292127

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?   Yes ⬤

                                                                                                                   No ◯

Continuing Flag   1

US3292127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 OCT 2020 14:22:46
Patient Cloud Open Date & Time	11 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

US3292127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 OCT 2020 11:30:51
Patient Cloud Open Date & Time	18 OCT 2020 00:01
Patient Cloud Close Date & Time	22 OCT 2020 23:59

US3292127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 OCT 2020 14:46:29
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

US3292127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 NOV 2020 10:40:46
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3292127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 NOV 2020 09:43:19
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 NOV 2020 09:29:20
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have 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 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚫
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⚫ Yes ⚪
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⚫ Yes ⚪
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚫
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚫
Date and time of submission	05 DEC 2020 09:13:02
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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	12 DEC 2020 08:33:19
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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 ◯

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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 ○

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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	01 JAN 2021 21:06:50
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 JAN 2021 11:46:08
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 14:52:46
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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	25 JAN 2021 12:48:47
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬤
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Date and time of submission	29 JAN 2021 12:18:12
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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	08 FEB 2021 07:11:43
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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	12 FEB 2021 13:40:28
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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 ○

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 FEB 2021 11:28:54
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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	05 MAR 2021 13:40:05
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 MAR 2021 09:24:35
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 MAR 2021 11:08:47
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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	27 MAR 2021 16:26:44
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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	01 APR 2021 13:49:16
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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 ◯

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 APR 2021 11:43:10
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 APR 2021 15:15:23
Patient Cloud Open Date & Time	22 APR 2021 00:01
Patient Cloud Close Date & Time	26 APR 2021 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 APR 2021 14:18:54
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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):

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-2022-1614-1665399

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

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

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 ⃝

FDA-CBER-2022-1614-1665403

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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):

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 ⭘

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 ◯

FDA-CBER-2022-1614-1665409

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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):

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 ⭕

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT **DAY 320**

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

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

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

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

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT   DAY 334

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

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

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

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

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have 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-2022-1614-1665419

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	**DAY 348**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭘
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭘
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 ◯

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

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

Fever (Temperature $\geq$ 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 ◯

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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):

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 ⭕

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	**DAY 383**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have 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-2022-1614-1665431

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 ◯

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT   **DAY 397**

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

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

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

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT   **DAY 411**

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

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

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

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

FDA-CBER-2022-1614-1665439

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT   **DAY 418**

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

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

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

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	30 SEP 2021 00:01
Patient Cloud Close Date & Time	04 OCT 2021 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

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

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

FDA-CBER-2022-1614-1665443

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 ⭕

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

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

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

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 ⃝

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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-2022-1614-1665457

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	**DAY 481**

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

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

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

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

FDA-CBER-2022-1614-1665459

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 ◯

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 ◯

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○

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

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

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 ⭕

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	**DAY 516**

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

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

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

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

FDA-CBER-2022-1614-1665469

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 ◯

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 ⭕

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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):

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 ⃝

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

DAY 551

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

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

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-2022-1614-1665479

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 ⃝

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 565

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

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

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

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

FDA-CBER-2022-1614-1665483

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

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

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 ◯

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 ⭕

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT **DAY 593**

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

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

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

FDA-CBER-2022-1614-1665491

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 600

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

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

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 ⭕

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	**DAY 614**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○

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

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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-2022-1614-1665501

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	28 APR 2022 00:01
Patient Cloud Close Date & Time	02 MAY 2022 23:59

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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-2022-1614-1665503

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 ◯

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT **DAY 649**

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

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

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

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 ◯

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	**DAY 670**

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

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

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

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

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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	⬭

FDA-CBER-2022-1614-1665515

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	**DAY 691**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 ≥ 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 ○

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 ◯

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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):

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-2022-1614-1665533

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT DAY 747

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

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

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

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

TIMEPOINT DAY 754

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

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

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

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

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT   **DAY 761**

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

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

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

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

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT	**DAY 768**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 ◯

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT **DAY 782**

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

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

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

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 ◯

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

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

US3292127

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:21:43

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		05 MAR 2021 13:40:27

US3292127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*	3 NOV 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3292127

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

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

Continuing Flag	1

US3292127
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **22 Feb 2021 18:47:41**
Generated On: 09 Jun 2021 16:21:43

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*	7 DEC 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3292127

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?   Yes ●

                                                                    No ◯

Continuing Flag   1

US3292127
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **22 Feb 2021 18:47:41**
Generated On: 09 Jun 2021 16:21:43

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

Date of Contact or Contact Attempt *(dd MMM yyyy)* — 5 JAN 2021

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

Comments

If Contact Not Made, please provide Comments _____

US3292127

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?   Yes ●

                                                            No ○

Continuing Flag   1

US3292127
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **03 Mar 2021 14:12:23**
Generated On: 09 Jun 2021 16:21:43

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 4 FEB 2021 |

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

Comments

If Contact Not Made, please provide Comments

US3292127

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) **03 Mar 2021 14:12:23**

Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?   Yes ●

                                                                          No ◯

Continuing Flag   1

Data signed: (b) (4) **08 Apr 2021 16:15:34**
Generated On: 09 Jun 2021 16:21:43

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	5 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT4

US3292127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) **08 Apr 2021 16:15:34**

Generated On: 09 Jun 2021 16:21:43

Were vital signs assessed?	Yes ⭕
	No ⬤

Date of assessment *(dd MMM yyyy)* _____

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

Vital Signs Date and Time (derived) _____

Temperature *(xxx.x)* _____

Route of measurement	Oral ⭕
	Axillary ⭕
	Other ⭕

If Other, specify _____

Pulse *(xxx)* _____

Pulse units _____

Respiratory Rate *(xxx)* _____

Respiratory Rate units _____

Systolic Blood Pressure *(xxx)* _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure *(xxx)* _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3292127

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) **08 Apr 2021 16:15:34**

Generated On: 09 Jun 2021 16:21:43

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.

US3292127

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **08 Apr 2021 16:15:34**

Generated On: 09 Jun 2021 16:21:43

Was the sample collected?	Yes ⬤
	No ⭕

Collection date *(dd MMM yyyy)*	05 MAR 2021
Collection time *(00:00-23:59)*	12:04 (24 HR)
Collection date and time (derived)	05 MAR 2021 12:04

US3292127

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) **08 Apr 2021 16:15:34**

Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?   Yes ●

                                                                                   No ○

Continuing Flag   1

US3292127
Folder: Safety Call Day 239 (1)
Form: Safety Call
Data signed: (b) (4) **16 Apr 2021 14:03:06**
Generated On: 09 Jun 2021 16:21:43

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*	6 APR 2021
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments _____

US3292127

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) **16 Apr 2021 14:03:06**

Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?   Yes ●

                                            No ○

Continuing Flag   1

US3292127
Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43

Was Contact Attempted?	Yes ◯
	No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)* _____

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

Comments

If Contact Not Made, please provide Comments _____

Is the participant continuing to the next visit?   Yes ◯

No ◯

Continuing Flag

US3292127
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 16:21:43

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

Type of Contact

Clinic Visit - Scheduled ⬭

Clinical Visit - Unscheduled ⬭

Safety Call ⬭

Convalescent Tele-visit ⬭

Has the subject reported symptoms of SARS-COV-2?

Yes ⬭

No ⬭

Generate Next COVID-19 Assessment   Yes ◯

                                                                      No ◯

US3292127

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

Form: Visit Date

Data signed: (b) (4) **22 Feb 2021 18:47:40**

Generated On: 09 Jun 2021 16:21:43

Was this visit performed?	Yes ⬤
	No ◯

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

Folder OID	UNBLND_DECIDE

US3292127
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **08 Apr 2021 16:15:34**
Generated On: 09 Jun 2021 16:21:43

Date of updated informed consent *(dd MMM yyyy)*	28 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False

Was the participant unblinded?	Yes	⬤
	No	◯

Under what version of the Protocol was the Participant unblinded?	Amendment 5	◯
	Amendment 6 or later	⬤

Date of unblinding *(dd MMM yyyy)*	28 JAN 2021

Participant randomization assignment	mRNA-1273	◯
	Placebo	⬤

Actual Dose 1	mRNA-1273	◯
	Placebo	⬤
	Not Administered	◯

Actual Dose 2	mRNA-1273	◯
	Placebo	⬤
	Not Administered	◯

Will participant receive mRNA-1273?	Yes	⬤
	No	◯

Placebo Only Flag	1
Continuing with mRNA-1273	1

US3292127
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Data signed: (b) (4) **22 Feb 2021 18:47:40**
Generated On: 09 Jun 2021 16:21:43

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

US3292127

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **22 Feb 2021 18:47:40**

Generated On: 09 Jun 2021 16:21:43

Height	ND - Not Done
Weight	ND - Not Done
BMI *(xxx.x)*	
Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	28 JAN 2021
Time of assessment *(00:00-23:59)*	14:37 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 14:37
Temperature *(xxx.x)*	37.1 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	81 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	162 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	91 mmHg
Diastolic Blood Pressure units	MMHG

US3292127

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **22 Feb 2021 18:47:40**

Generated On: 09 Jun 2021 16:21:43

Height	ND - Not Done
Weight	ND - Not Done
BMI *(xxx.x)*	
Timepoint	Pre-Dose ○
	Post-Dose ●
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	28 JAN 2021
Time of assessment *(00:00-23:59)*	15:53 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 15:53
Temperature *(xxx.x)*	36.5 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	78 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	176 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	91 mmHg
Diastolic Blood Pressure units	MMHG

US3292127

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

Form: Physical Examination

Data signed: (b) (4) **22 Feb 2021 18:47:40**

Generated On: 09 Jun 2021 16:21:43

| Was the physical examination performed? | Yes ● |
| | No ○ |

| Date of examination *(dd MMM yyyy)* | 28 JAN 2021 |

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

US3292127

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

Form: Exposure

Data signed: (b) (4) **22 Feb 2021 18:47:40**

Generated On: 09 Jun 2021 16:21:43

Was study treatment given?	Yes ●
	No ○

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

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	28 JAN 2021
What was the treatment time? *(00:00-23:59)*	15:23 (24 HR)
Treatment Date and Time (derived)	28 JAN 2021 15:23
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

US3292127

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

Form: Immunogenicity Assessment

Data signed: (b) (4) **22 Feb 2021 18:47:40**

Generated On: 09 Jun 2021 16:21:43

Was the sample collected?	Yes ⬤
	No ◯

Collection date *(dd MMM yyyy)*	28 JAN 2021
Collection time *(00:00-23:59)*	14:50 (24 HR)
Collection date and time (derived)	28 JAN 2021 14:50

US3292127

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **22 Feb 2021 18:47:36**

Generated On: 09 Jun 2021 16:21:43

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

US3292127

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

Form: Continuing

Data signed: (b) (4) **22 Feb 2021 18:47:40**

Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3292127

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*	5 FEB 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3292127

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) **22 Feb 2021 18:47:41**

Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?   Yes ●

                                                                    No ◯

Continuing Flag	1
OLD29 Placebo Flag	1

US3292127
Folder: OL-D29 (1)
Form: Visit Date
Data signed: (b) (4) **03 Mar 2021 14:12:22**
Generated On: 09 Jun 2021 16:21:43

Was this visit performed?	Yes ⬤
	No ◯

Visit date (dd MMM yyyy)	26 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

Folder OID	OLD29

US3292127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **03 Mar 2021 14:12:22**

Generated On: 09 Jun 2021 16:21:43

Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	26 FEB 2021
Time of assessment *(00:00-23:59)*	13:03 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 13:03
Temperature *(xxx.x)*	36.9 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	79 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	151 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	76 mmHg
Diastolic Blood Pressure units	MMHG

US3292127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **03 Mar 2021 14:12:22**

Generated On: 09 Jun 2021 16:21:43

Timepoint	Pre-Dose ⭕
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ⭕
Date of assessment *(dd MMM yyyy)*	26 FEB 2021
Time of assessment *(00:00-23:59)*	14:30 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 14:30
Temperature *(xxx.x)*	36.2 C
Route of measurement	Oral ⬤
	Axillary ⭕
	Other ⭕
If Other, specify	
Pulse *(xxx)*	80 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	96 mmHg
Diastolic Blood Pressure units	MMHG

US3292127

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) **03 Mar 2021 14:12:22**

Generated On: 09 Jun 2021 16:21:43

Was the physical examination performed?   Yes ●

No ○

Date of examination *(dd MMM yyyy)*   26 FEB 2021

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

Was study treatment given?	Yes ●
	No ○

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

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	26 FEB 2021
What was the treatment time? *(00:00-23:59)*	14:00 (24 HR)
Treatment Date and Time (derived)	26 FEB 2021 14:00
Which arm was used to give treatment?	Left Arm ●
	Right Arm ○
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

FDA-CBER-2022-1614-1665587

US3292127

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) **03 Mar 2021 14:12:22**

Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?　　　　　　　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ○

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　　　　　1

US3292127

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) **08 Apr 2021 16:15:34**

Generated On: 09 Jun 2021 16:21:43

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 5 MAR 2021 |

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

Comments

If Contact Not Made, please provide Comments

US3292127

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) **08 Apr 2021 16:15:34**

Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3292127
Folder: OL-D57 (1)
Form: Visit Date
Data signed: (b) (4) **08 Apr 2021 16:15:33**
Generated On: 09 Jun 2021 16:21:43

Was this visit performed?	Yes ⬤
	No ⭕
Visit date (dd MMM yyyy)	26 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ⭕
	Clinic ⬤
Folder OID	OLD57

US3292127

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) **08 Apr 2021 16:15:33**

Generated On: 09 Jun 2021 16:21:43

Were vital signs assessed?	Yes ◯
	No ⬤

Date of assessment *(dd MMM yyyy)* _____

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

Vital Signs Date and Time (derived) _____

Temperature *(xxx.x)* _____

Route of measurement	Oral ◯
	Axillary ◯
	Other ◯

If Other, specify _____

Pulse *(xxx)* _____

Pulse units _____

Respiratory Rate *(xxx)* _____

Respiratory Rate units _____

Systolic Blood Pressure *(xxx)* _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure *(xxx)* _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3292127
Folder: OL-D57 (1)
Form: Physical Examination
Data signed: (b) (4) **08 Apr 2021 16:15:33**
Generated On: 09 Jun 2021 16:21:43

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.

US3292127

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **08 Apr 2021 16:15:33**

Generated On: 09 Jun 2021 16:21:43

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	26 MAR 2021
Collection time *(00:00-23:59)*	12:52 (24 HR)
Collection date and time (derived)	26 MAR 2021 12:52

US3292127

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **22 Feb 2021 18:47:36**

Generated On: 09 Jun 2021 16:21:43

Did the participant experience any adverse events?   Yes ●

                                                                    No ◯

If Yes, enter details on the Adverse Events form.

US3292127

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **29 Apr 2021 17:56:31**

Generated On: 09 Jun 2021 16:21:43

AEID	USA-US072-2020-MRNA-1273-P30 1000015
Adverse event	MOTOR VEHICLE ACCIDENT

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)*	25 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)*	25 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)*	25 NOV 2020
Hospital Discharge Date *(dd MMM yyyy)*	04 DEC 2020

Admitted to ICU? Yes ○ No ● Unknown ○

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

Relationship to investigational product

- Not Related ●
- Related ○
- Not Applicable ○

Relationship to Study Procedure

- Not Related ●
- Related ○
- Not Applicable ○

Action taken with investigational product

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

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome

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

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

Narrative

PT'S SISTER CALLED TODAY TO
REPORT THAT PATIENT WAS IN
A CAR ACCIDENT ON
25NOV2020. PT HAS BEEN
ADMITTED TO THE HOSPITAL
AND REMAINS ADMITTED. PT
REPORTEDLY HAS VASCULAR
DAMAGE TO HIS RIGHT CALF.
PT HAS ALSO REPORTEDLY
UNDERGONE THREE
SURGERIES TO RIGHT CALF,
THOUGH SPECIFICS WILL BE
REQUESTED ALONG WITH
MEDICAL RECORDS. NO PLANS
FOR DISCHARGE AT THE
MOMENT. WILL FOLLOW UP
ONCE PATIENT IS STABILIZED
AND ABLE TO GIVE A REPORT
TO STAFF. MEDICAL RECORDS
WILL ALSO BE COLLECTED.

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

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Folder: Adverse Events
Form: Adverse Events (2)
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AEID	USA-US072-2020-MRNA-1273-P30 1000015
Adverse event	INTERNAL GI HEMORRHAGE - MOTOR VEHICAL ACCIDENT

Was this a medically-attended AE?   Yes ⬤   No ◯

Was this a Solicited Adverse Reaction?   Yes ◯   No ⬤

Is this event a confirmed diagnosis of Symptomatic Covid-19?   Yes ◯   No ⬤

Start date *(dd MMM yyyy)*	13 DEC 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?   Yes ◯   No ⬤

If not Ongoing, end date *(dd MMM yyyy)*	11 JAN 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

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

Is the adverse event serious?   Yes ⬤   No ◯

AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	17 DEC 2020
Hospital Discharge Date *(dd MMM yyyy)*	11 JAN 2021

Admitted to ICU?   Yes ◯   No ⬤   Unknown ◯

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

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

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

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

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	True

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

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

Narrative

PATIENT WAS IN CLINIC FOR DECISION VISIT ON 28JAN2021 AND INFORMED STAFF THAT HE HAD BEEN HOSPITALIZED ONCE AGAIN FOLLOWING A RECENT HOSPITALIZATION FOR A PREVIOUSLY REPORTED SAE. PATIENT STATES THAT DOCTORS DISCOVERED INTERNAL BLEEDING AT TWO DIFFERENT SITES INTERNALLY. PATIENT CANNOT SPECIFY WHICH SITES. PATIENT WAS UNABLE TO DESCRIBE MEDICATIONS OR PROCEDURES COMPLETED. PATIENT STATES THAT SURGERY FINALLY CONTROLLED AND STOPPED THE BLEED ON 29DEC2020, BUT HE REMAINED HOSPITALIZED. MEDICAL RECORDS WILL BE REQUESTED ASAP.

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) **29 Apr 2021 17:56:31**

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AEID	
Adverse event	RIGHT CALF HEMATOMA
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)*	25 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)*	4 JAN 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ◯
	Grade 2/Moderate ◯
	Grade 3/Severe ⬤
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	

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

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

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

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

Other action taken (check all that apply)

None	False
Concomitant Medication	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	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

AEID	
Adverse event	LEFT FOREARM SKIN TEAR
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)*	25 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)*	14 DEC 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ◯
	Grade 2/Moderate ⬤
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤

AE is serious due To (check all that apply)

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

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

Relationship to investigational product

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Relationship to Study Procedure

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Action taken with investigational product

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

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

Outcome

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

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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AEID	
Adverse event	GENERAL LOCALIZED PAIN SECONDARY TO MVA
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)*	25 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)*	04 JAN 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ○
	Grade 2/Moderate ●
	Grade 3/Severe ○
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○

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

Relationship to investigational product	Not Related ⬤
	Related ◯
	Not Applicable ◯
Relationship to Study Procedure	Not Related ⬤
	Related ◯
	Not Applicable ◯
Action taken with investigational product	None ⬤
	Dose Delayed ◯
	Investigational Product Withdrawn ◯
	Not Applicable ◯

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

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

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	GENERAL LOCALIZED PAIN DUE TO MOTOR VEHICLE ACCIDENT
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events
Form: Adverse Events (6)
Data signed: (b) (4) **29 Apr 2021 17:56:31**
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AEID	
Adverse event	BLUNT INJURY TO RLE
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)*	25 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)*	
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ○
	Grade 2/Moderate ○
	Grade 3/Severe ●
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○
Number of Days in ICU	

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

AEID	
Adverse event	C6-C7 LIGAMENTOUS INJURY

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)*	25 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)*	
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

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

Is the adverse event serious?
- Yes ○
- No ●

AE is serious due To (check all that apply)

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

Admitted to ICU?
- Yes ○
- No ○
- Unknown ○

Number of Days in ICU	

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

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

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

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

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

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

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SECONDARY TO MVA
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) **29 Apr 2021 17:56:31**

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AEID	
Adverse event	PUNCTATE LACERATION ANTERIOR SCALP
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)*	25 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)*	07 JAN 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ○
	Grade 2/Moderate ○
	Grade 3/Severe ●
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○

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

Relationship to investigational product

- Not Related ●
- Related ○
- Not Applicable ○

Relationship to Study Procedure

- Not Related ●
- Related ○
- Not Applicable ○

Action taken with investigational product

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

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

Outcome

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

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SECONDARY TO MVA
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events
Form: Adverse Events (9)
Data signed: (b) (4) **29 Apr 2021 17:56:31**
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AEID	
Adverse event	SEVER PROSTATOMEGALY
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)*	25 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)*	01 JAN 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ○
	Grade 2/Moderate ○
	Grade 3/Severe ●
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○
Number of Days in ICU	

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

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

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

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

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

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

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SECONDARY TO MVA
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events
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Data signed: (b) (4) **29 Apr 2021 17:56:31**
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AEID	
Adverse event	LEFT PLEURAL EFFUSION
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)*	25 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 JAN 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ○
	Grade 2/Moderate ○
	Grade 3/Severe ●
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●

AE is serious due To (check all that apply)

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

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Form: Adverse Events (10)

Data signed: (b) (4) **29 Apr 2021 17:56:31**

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

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

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

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

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

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

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SECONDARY TO MVA
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **22 Feb 2021 18:47:36**

Generated On: 09 Jun 2021 16:21:43

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

No ○

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

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) **29 Apr 2021 17:56:31**

Generated On: 09 Jun 2021 16:21:43

Name of Medication	VITAMIN D
Prophylaxis	Yes ●
	No ○
Indication	SUPPLEMENT
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 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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **29 Apr 2021 17:56:31**
Generated On: 09 Jun 2021 16:21:43

Name of Medication	LISINOPRIL

Prophylaxis	Yes ○
	No ●

Indication	HYPERTENSION
Dose per administration	20

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

If dose unit is Other, specify	

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

If frequency is Other, specify	

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

	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 2013
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 ●

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Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **29 Apr 2021 17:56:31**
Generated On: 09 Jun 2021 16:21:43

Name of Medication	AMLODIPINE

Prophylaxis	Yes ⬭
	No ⬤

Indication	HYPERTENSION
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 2013
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) **29 Apr 2021 17:56:31**
Generated On: 09 Jun 2021 16:21:43

Name of Medication	SIMVASTATIN
Prophylaxis	Yes ⭘
	No ⬤
Indication	HYPERCHOLESTEROL
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 ⭘

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EAB) (1725)

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **29 Apr 2021 17:56:31**
Generated On: 09 Jun 2021 16:21:43

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2016
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Data signed: (b) (4) **29 Apr 2021 17:56:31**
Generated On: 09 Jun 2021 16:21:43

Name of Medication	HYDROCHLOROTHIAZIDE (HCTZ)
Prophylaxis	Yes ◯
	No ⬤
Indication	HYPERTENSION
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	◯
Intraperitoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2013
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 ●

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) **29 Apr 2021 17:56:31**

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Name of Medication	POTASSIUM
Prophylaxis	Yes ●
	No ○
Indication	SUPPLEMENT
Dose per administration	10
Dose unit	mg ●
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○
If dose unit is Other, specify	
Frequency	once daily ●
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2013
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 ⬤

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) **29 Apr 2021 17:56:31**

Generated On: 09 Jun 2021 16:21:43

Name of Medication	MULTIVITAMINS

Prophylaxis	Yes	⬤
	No	◯

Indication	SUPPLEMENT
Dose per administration	1

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

If dose unit is Other, specify	

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

If frequency is Other, specify	

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

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 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)	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)   **29 Apr 2021 17:56:31**
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Name of Medication	POTASSIUM

Prophylaxis	Yes ●
	No ○

Indication	SUPPLEMENT
Dose per administration	10

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

If dose unit is Other, specify	MEQ

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 2013
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Name of Medication	ASPIRIN
Prophylaxis	Yes ●
	No ○
Indication	PROPHYLAXIS FOR THE GENERAL CARDIAC HEALTH
Dose per administration	81
Dose unit	mg ●
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○
If dose unit is Other, specify	
Frequency	once daily ●
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○

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

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) **29 Apr 2021 17:56:31**

Generated On: 09 Jun 2021 16:21:43

Name of Medication	TRAMADOL
Prophylaxis	Yes ⬭
	No ⬤
Indication	GENERAL LOCALIZED PAIN FROM MOTOR VEHICLE ACCIDENT
Dose per administration	50
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)*	30 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ○
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	4 JAN 2021
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 (11)
Data signed: (b) (4) **29 Apr 2021 17:56:31**
Generated On: 09 Jun 2021 16:21:43

Name of Medication	HYDROMORPHONE

Prophylaxis
- Yes ⚪
- No ⬤

Indication	PAIN FROM MOTOR VEHICLE ACCIDENT
Dose per administration	0.2

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)*	27 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ⃝
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	27 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 ⃝

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Data signed: (b) (4) **29 Apr 2021 17:56:31**
Generated On: 09 Jun 2021 16:21:43

Name of Medication	GABAPENTIN
Prophylaxis	Yes ◯
	No ⬤
Indication	PAIN FROM MOTOR VEHICLE ACCIDENT
Dose per administration	300
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 ◯

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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)*	17 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	11 JAN 2021
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 (13)
Data signed: (b) (4) **29 Apr 2021 17:56:31**
Generated On: 09 Jun 2021 16:21:43

Name of Medication	SENNA GLYCOSIDE
Prophylaxis	Yes ⚪
	No ⬤
Indication	INTERNAL GI HEMORRHAGE - MOTOR VEHICAL ACCIDENT
Dose per administration	17.2
Dose unit	mg ⬤
	ug ⚪
	mL ⚪
	g ⚪
	IU ⚪
	tablet ⚪
	capsule ⚪
	puff ⚪
	Other ⚪
If dose unit is Other, specify	
Frequency	once daily ⚪
	twice daily ⚪
	three times daily ⚪
	four times daily ⚪
	every other day ⚪
	every week ⚪
	every month ⚪
	as needed ⚪
	once ⚪
	unknown ⚪
	other ⬤
If frequency is Other, specify	EVERY NIGHT AT BEDTIME
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)*	17 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	11 JAN 2021
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 (14)

Data signed: (b) (4) **29 Apr 2021 17:56:31**

Generated On: 09 Jun 2021 16:21:43

Name of Medication	POTASSIUM PHOSPHATE IN NORMAL SALINE
Prophylaxis	Yes ○
	No ●
Indication	INTERNAL GI HEMORRHAGE - MOTOR VEHICAL ACCIDENT
Dose per administration	15
Dose unit	mg ○
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ●
If dose unit is Other, specify	MMOL
Frequency	once daily ○
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ●
If frequency is Other, specify	EVERY THREE HOURS
Route of administration	Oral ○
	Topical ○
	Subcutaneous ○
	Transdermal ○

PRODUCTION RELEASE (v12.003
EAB) (1725)

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)*	17 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ○
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	11 JAN 2021
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	SIMVASTATIN

Prophylaxis	Yes ◯
	No ⬤

Indication	MOTOR VEHICLE ACCIDENT
Dose per administration	20

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

If dose unit is Other, specify	

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

If frequency is Other, specify	QHS

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

FDA-CBER-2022-1614-1665647

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)* — 17 DEC 2020

Start date completely unknown — False

Ongoing? Yes ◯ No ⬤

If not Ongoing, End date *(dd MMM yyyy)* — 11 JAN 2021

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 (16)
Data signed: (b) (4) **29 Apr 2021 17:56:31**
Generated On: 09 Jun 2021 16:21:43

Name of Medication	DECADRON
Prophylaxis	Yes ⚪
	No ⚫
Indication	MOTOR VEHICLE ACCIDENT
Dose per administration	10
Dose unit	mg ⚫
	ug ⚪
	mL ⚪
	g ⚪
	IU ⚪
	tablet ⚪
	capsule ⚪
	puff ⚪
	Other ⚪
If dose unit is Other, specify	
Frequency	once daily ⚪
	twice daily ⚪
	three times daily ⚫
	four times daily ⚪
	every other day ⚪
	every week ⚪
	every month ⚪
	as needed ⚪
	once ⚪
	unknown ⚪
	other ⚪
If frequency is Other, specify	
Route of administration	Oral ⚪
	Topical ⚪
	Subcutaneous ⚪
	Transdermal ⚪
	Intraocular ⚪

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	17 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ○
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	11 JAN 2021
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 (17)
Data signed: (b) (4)   **29 Apr 2021 17:56:31**
Generated On: 09 Jun 2021 16:21:43

Name of Medication	OMNIPAQUE 350 MG/ML
Prophylaxis	Yes ◯
	No ⬤
Indication	MOTOR VEHICLE ACCIDENT
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)*	17 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	17 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) **29 Apr 2021 17:56:31**

Generated On: 09 Jun 2021 16:21:43

Name of Medication	DOCUSATE SODIUM
Prophylaxis	Yes ⚪
	No ⚫
Indication	MOTOR VEHICLE ACCIDENT
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)*	30 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	4 DEC 2020
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 ⬤

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) **29 Apr 2021 17:56:31**

Generated On: 09 Jun 2021 16:21:43

Name of Medication	ENOXAPARIN
Prophylaxis	Yes ⬭
	No ⬤
Indication	MOTOR VEHICLE ACCIDENT
Dose per administration	30
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)*	30 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤

If not Ongoing, End date *(dd MMM yyyy)*	4 DEC 2020
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 ⬤

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) **29 Apr 2021 17:56:31**

Generated On: 09 Jun 2021 16:21:43

Name of Medication	MORPHINE SULFATE
Prophylaxis	Yes ○
	No ●
Indication	MOTOR VEHICLE ACCIDENT
Dose per administration	2
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)*	26 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ○
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	4 DEC 2020
Was this medication taken for solicited event?	Yes ○
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ○
	803 ○
	804 ○

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) **29 Apr 2021 17:56:31**

Generated On: 09 Jun 2021 16:21:43

Name of Medication	ONDANSETRON
Prophylaxis	Yes ○
	No ●
Indication	MOTOR VEHICLE ACCIDENT
Dose per administration	4
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)*	25 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	4 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **03 Mar 2021 14:12:22**

Generated On: 09 Jun 2021 16:21:43

Were any concomitant procedures performed?   Yes ●

No ◯

If yes, please complete Concomitant Procedures form.

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) **23 Apr 2021 18:32:38**

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
25 NOV 2020	FOUR COMPARTMENT FASCIOTOMY (RLE)	Adverse Event	
28 NOV 2020	DEBRIDEMENT RLE WOUND VAC PLACEMENT	Adverse Event	
01 DEC 2020	EXCISIONAL DEBRIDEMENT RLE WOUND VAC PLACEMENT	Adverse Event	
25 NOV 2020	CT ABDOMINAL PELVIS	Adverse Event	
18 DEC 2020	DEBRIDEMENT OF WOUND	Adverse Event	
19 DEC 2020	EGD	Diagnostic	
20 DEC 2020	BLOOD TRANSFUSION	Adverse Event	
22 DEC 2020	BLOOD TRANSFUSION	Adverse Event	
21 DEC 2020	EGD	Diagnostic	
23 DEC 2020	BLOOD TRANSFUSION	Adverse Event	
25 DEC 2020	BLOOD TRANSFUSION	Adverse Event	
27 DEC 2020	BLOOD TRANSFUSION	Adverse Event	
28 DEC 2020	BLOOD TRANSFUSION	Adverse Event	
21 DEC 2020	HEMOSTATIC CLIPS	Adverse Event	
21 DEC 2020	COLONOSCOPY	Diagnostic	
28 DEC 2020	EGD	Diagnostic	
28 DEC 2020	HEMOSTATIC CLIPS	Adverse Event	
17 DEC 2020	DOPPLER ULTRASOUND	Diagnostic	
1 JAN 2021	DOPPLER ULTRASOUND	Diagnostic	

PRODUCTION RELEASE (v12.003 EAB) (1725)

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
17 DEC 2020	CHEST X-RAY	Diagnostic	
28 DEC 2020	CHEST X-RAY	Diagnostic	
29 DEC 2020	CHEST X-RAY	Diagnostic	
30 DEC 2020	CHEST X-RAY	Diagnostic	
29 DEC 2020	EMBOLIZATION	Adverse Event	
29 DEC 2020	CT-ABDOMEN	Diagnostic	

FDA-CBER-2022-1614-1665663

US3292127
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 09 Jun 2021 16:21:43

Date of dosing discontinuation (dd MMM yyyy) _____

Primary reason for dosing discontinuation

AE (specify) ◯
SAE (specify) ◯
Death ◯
Lost To Follow-up ◯
Physician decision (specify) ◯
Pregnancy ◯
Protocol deviation (specify) ◯
Study Terminated By Sponsor ◯
Withdrawal of consent by participant (specify) ◯
Due to SARS-COV-2 ◯
Other ◯

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

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

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

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

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

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

Was autopsy performed?	
Yes	◯
No	◯
Unknown	◯

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) **29 Apr 2021 17:56:32**

Generated On: 09 Jun 2021 16:21:43

SAEID	USA-US072-2020-MRNA-1273-P30 1000015
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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form (1)
Data signed: (b) (4) **29 Apr 2021 17:56:32**
Generated On: 09 Jun 2021 16:21:43

SAEID	USA-US072-2020-MRNA-1273-P30 1000015
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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	03/DEC/2020 16:56
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

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form (2)
Data signed: (b) (4) **29 Apr 2021 17:56:32**
Generated On: 09 Jun 2021 16:21:43

SAEID	USA-US072-2020-MRNA-1273-P30 1000015
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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	11/DEC/2020 10:58
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

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form (3)
Data signed: (b) (4) **29 Apr 2021 17:56:32**
Generated On: 09 Jun 2021 16:21:43

SAEID	USA-US072-2020-MRNA-1273-P30 1000015
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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	22/FEB/2021 10:07
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

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Data signed: (b) (4) **29 Apr 2021 17:56:32**

Generated On: 09 Jun 2021 16:21:43

SAEID	USA-US072-2020-MRNA-1273-P30 1000015
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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	01/MAR/2021 15:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form (5)
Data signed: (b) (4) **29 Apr 2021 17:56:32**
Generated On: 09 Jun 2021 16:21:43

SAEID	USA-US072-2020-MRNA-1273-P30 1000015
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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	12/APR/2021 12:31
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

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form (6)
Data signed: (b) (4) **29 Apr 2021 17:56:32**
Generated On: 09 Jun 2021 16:21:43

SAEID	USA-US072-2020-MRNA-1273-P30 1000015
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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	14/APR/2021 10:50
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form (7)

Data signed: (b) (4) **29 Apr 2021 17:56:32**

Generated On: 09 Jun 2021 16:21:43

SAEID	USA-US072-2020-MRNA-1273-P30 1000015
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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	20/APR/2021 09:41
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form (8)
Data signed: (b) (4) **29 Apr 2021 17:56:32**
Generated On: 09 Jun 2021 16:21:43

SAEID	USA-US072-2020-MRNA-1273-P30 1000015
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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	22/APR/2021 09:56
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

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form (9)
Data signed: (b) (4) **29 Apr 2021 17:56:32**
Generated On: 09 Jun 2021 16:21:43

SAEID	USA-US072-2020-MRNA-1273-P30 1000015
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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	23/APR/2021 11:00
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

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form (10)
Data signed: (b) (4) **29 Apr 2021 17:56:32**
Generated On: 09 Jun 2021 16:21:43

SAEID	USA-US072-2020-MRNA-1273-P30 1000015
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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	29/APR/2021 06:20
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

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Data signed: (b) (4) **22 Feb 2021 18:47:41**
Generated On: 09 Jun 2021 16:21:43

SAEID	USA-US072-2021-MRNA-1273-P30 1000012
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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form (1)
Data signed: (b) (4) **22 Feb 2021 18:47:41**
Generated On: 09 Jun 2021 16:21:43

SAEID	USA-US072-2021-MRNA-1273-P30 1000012
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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	01/FEB/2021 12:45
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

US3292127 (Prod: Clinical Trials of Texas, Inc)

US3292127

Form: Participant Creation

Generated On: 09 Jun 2021 16:21:43

Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:08
User entered 'US3292127'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 17:44:12

US3292127
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:21:43

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:23:04
User entered 'Yes (Y)'		12 Aug 2020 17:11:43

US3292127
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:21:43
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:23:04
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 17:45:15

US3292127
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:21:43

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 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:23:04
User entered 'Clinic (Clinic)'		12 Aug 2020 17:11:43

US3292127
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:21:43
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered 'SCRN'	System	12 Aug 2020 17:11:43

US3292127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:21:43

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1 and Visit2 Day29: Year of Birth (1945) recorded on this form does not match with the Year of birth (1948) reported in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 12:15:33
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1 and Visit2 Day29: Year of Birth (1945) recorded on this form does not match with the Year of birth (1948) reported in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' answered with 'CRC updating' (Site from DM).	Dawn Killian (b) (4) (b) (4)	20 Oct 2020 19:21:49
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1 and Visit2 Day29: Year of Birth (1945) recorded on this form does not match with the Year of birth (1948) reported in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 05:00:45
DataPoint Verified.		27 Aug 2020 17:23:21
User entered (b) (6) 1945'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 17:45:16

US3292127
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:21:43

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:23:21
User entered '74'		12 Aug 2020 17:12:10

US3292127
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:21:43
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered 'YEARS'	System	12 Aug 2020 17:12:10

US3292127
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:21:43
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered '74'	System	11 Aug 2020 19:14:46

US3292127
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:21:43
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:23:21
User entered 'Male (M)'		12 Aug 2020 17:12:10

US3292127
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:21:43
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:23:21
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'		12 Aug 2020 17:12:10

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:23:21
User entered '1'		12 Aug 2020 17:12:10

US3292127
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:21:43
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:23:21
User entered '0'		12 Aug 2020 17:12:10

US3292127
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:21:43
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:23:21
User entered '0'		12 Aug 2020 17:12:10

US3292127
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:21:43
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:23:21
User entered '0'		12 Aug 2020 17:12:10

US3292127
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:21:43

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:23:21
User entered '0'		12 Aug 2020 17:12:10

US3292127
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:21:43
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:23:21
User entered '0'		12 Aug 2020 17:12:10

US3292127
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:21:43
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:23:21
User entered empty.		12 Aug 2020 17:12:10

US3292127
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:21:43
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:23:21
User entered '0'		12 Aug 2020 17:12:10

US3292127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:21:43

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:23:21
User entered '0'		12 Aug 2020 17:12:10

US3292127
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:21:43

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:23:27
User entered '11 Aug 2020'		11 Aug 2020 19:14:46

US3292127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:21:43

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered 'Aug 2020'	System	11 Aug 2020 19:14:46

US3292127
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:21:43
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered '2020'	System	11 Aug 2020 19:14:46

US3292127
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:21:43
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:23:27
User entered 'Amendment 2 (2)'		11 Aug 2020 19:14:46

US3292127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:21:43

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:23:27
User entered 'Yes (Y)'		11 Aug 2020 19:14:46

US3292127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:21:43

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:23:27
User entered empty.		11 Aug 2020 19:14:46

US3292127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:21:43

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:23:27
User entered empty.		11 Aug 2020 19:14:46

US3292127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:21:43

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:23:27
User entered 'No (N)'		11 Aug 2020 19:14:46

US3292127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:21:43

If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:23:27
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 17:45:15

US3292127
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:21:43
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered '1'	System	11 Aug 2020 19:14:54

US3292127

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:21:43

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:23:51
User entered 'Yes (Y)'		11 Aug 2020 19:14:54

US3292127
Folder: Screening
Form: Medical History Summary
Generated On: 09 Jun 2021 16:21:43
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:26:01
User entered 'Yes (Y)'		12 Aug 2020 17:13:16

US3292127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:21:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:26:33
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Visual acuity reduced, LLT: Visual acuity decreased - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 18:38:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 18:38:16
Data point term sent to Coder	System	17 Aug 2020 18:36:49
User entered 'Decreased visual acuity' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 18:36:13
Data point term sent to Coder	System	12 Aug 2020 17:16:16
User entered 'Vision'	(b) (4), (b) (6)	12 Aug 2020 17:15:47

US3292127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:21:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:26:33
User entered 'un UNK 1953'		12 Aug 2020 17:15:47

US3292127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:21:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:26:33
User entered '0'		12 Aug 2020 17:15:47

US3292127
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:21:43
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:26:33
User entered 'Yes (Y)'		12 Aug 2020 17:15:47

US3292127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:26:33
User entered empty.		12 Aug 2020 17:15:47

US3292127
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:21:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:26:33
User entered '0'		12 Aug 2020 17:15:47

US3292127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:21:43

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered 'Jan 1953'	System	12 Aug 2020 17:15:47

US3292127
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:21:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered '1953'	System	12 Aug 2020 17:15:47

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:21:43

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered empty.	System	12 Aug 2020 17:15:47

US3292127
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:21:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered empty.	System	12 Aug 2020 17:15:47

US3292127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:21:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:26:33
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 18:38:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 18:38:16
Data point term sent to Coder	System	17 Aug 2020 18:36:53
User entered 'Hypercholesterolemia'	(b) (4), (b) (6)	17 Aug 2020 18:36:34

US3292127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:21:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:26:33
User entered 'un UNK 2016'		17 Aug 2020 18:36:34

US3292127
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:21:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:26:33
User entered '0'		17 Aug 2020 18:36:34

US3292127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:21:43

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:26:33
User entered 'Yes (Y)'		17 Aug 2020 18:36:34

US3292127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:26:33
User entered empty.		17 Aug 2020 18:36:34

US3292127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:21:43

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:26:33
User entered '0'		17 Aug 2020 18:36:34

US3292127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:21:43

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered 'Jan 2016'	System	17 Aug 2020 18:36:34

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:21:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered '2016'	System	17 Aug 2020 18:36:34

US3292127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:21:43

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered empty.	System	17 Aug 2020 18:36:34

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:21:43

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered empty.	System	17 Aug 2020 18:36:34

US3292127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:21:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:26:33
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)	17 Aug 2020 18:38:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 18:38:16
Data point term sent to Coder	System	17 Aug 2020 18:36:51
User entered 'Hypertension'	(b) (4), (b) (6)	17 Aug 2020 18:36:48

US3292127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:21:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:26:33
User entered 'un UNK 2013'		17 Aug 2020 18:36:48

US3292127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:21:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:26:33
User entered '0'		17 Aug 2020 18:36:48

US3292127
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:21:43
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:26:33
User entered 'Yes (Y)'		17 Aug 2020 18:36:48

US3292127
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:21:43
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:26:33
User entered empty.		17 Aug 2020 18:36:48

US3292127
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:21:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:26:33
User entered '0'		17 Aug 2020 18:36:48

Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:21:43

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered 'Jan 2013'	System	17 Aug 2020 18:36:48

US3292127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:21:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered '2013'	System	17 Aug 2020 18:36:48

US3292127
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:21:43
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered empty.	System	17 Aug 2020 18:36:48

US3292127
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:21:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered empty.	System	17 Aug 2020 18:36:48

US3292127
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:26:53
User entered 'Yes (Y)'		12 Aug 2020 17:20:35

US3292127
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:26:53
User entered '11 Aug 2020'		12 Aug 2020 17:20:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:26:53
User entered '13:00'		12 Aug 2020 17:20:35

US3292127
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered '11 Aug 2020 13:00'	System	12 Aug 2020 17:20:35

US3292127
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:26:53
User entered '176.3' cm		12 Aug 2020 17:20:35
DataPoint set to visible.	System	11 Aug 2020 19:14:54

US3292127
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:26:53
User entered '97.9' kg		12 Aug 2020 17:20:35
DataPoint set to visible.	System	11 Aug 2020 19:14:54

US3292127
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43

BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
Amendment Manager: User entered '31.49764'	System	16 Sep 2020 23:52:00
User entered '31.5'	System	12 Aug 2020 17:20:35
DataPoint set to visible.	System	11 Aug 2020 19:14:54

US3292127
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered 'kg/m2'	System	12 Aug 2020 17:20:35
DataPoint set to visible.	System	11 Aug 2020 19:14:54

US3292127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:43

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:26:53
User closed query 'Data is required. Please provide.' (Site from System).		14 Aug 2020 15:13:27
User entered missing code ND - Not Done; reason for change Data Entry Error		14 Aug 2020 01:58:20
Query 'Data is required. Please provide.' answered with 'Not done' (Site from System).		12 Aug 2020 17:20:44
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 17:20:35
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:20:35

US3292127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:43

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:26:53
User closed query 'Data is required. Please provide.' (Site from System).		19 Aug 2020 06:46:20
Query 'Data is required. Please provide.' answered with 'Not done' (Site from System).		12 Aug 2020 17:20:50
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 17:20:35
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:20:35

US3292127
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:26:53
User entered empty.		12 Aug 2020 17:20:35

US3292127
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:26:53
User closed query 'Data is required. Please provide.' (Site from System).		14 Aug 2020 15:13:31
User entered missing code ND - Not Done; reason for change Data Entry Error		14 Aug 2020 01:58:20
Query 'Data is required. Please provide.' answered with 'Not done' (Site from System).		12 Aug 2020 17:20:56
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 17:20:35
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:20:35

Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered 'bpm'	System	14 Aug 2020 01:58:20
User entered empty.	System	12 Aug 2020 17:20:35

US3292127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:43

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:26:53
User closed query 'Data is required. Please provide.' (Site from System).		14 Aug 2020 15:13:34
User entered missing code ND - Not Done; reason fo change Data Entry Error		14 Aug 2020 01:58:20
Query 'Data is required. Please provide.' answered with 'Not done' (Site from System).		12 Aug 2020 17:21:01
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 17:20:35
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:20:35

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered 'breaths/min'	System	14 Aug 2020 01:58:20
User entered empty.	System	12 Aug 2020 17:20:35

US3292127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:43

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:26:53
User closed query 'Data is required. Please provide.' (Site from System).		14 Aug 2020 15:13:36
User entered missing code ND - Not Done; reason for change Data Entry Error		14 Aug 2020 01:58:20
Query 'Data is required. Please provide.' answered with 'Not done' (Site from System).		12 Aug 2020 17:21:07
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 17:20:35
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:20:35

US3292127
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered 'mmHg'	System	14 Aug 2020 01:58:20
User entered empty.	System	12 Aug 2020 17:20:35

US3292127
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:26:53
User closed query 'Data is required. Please provide.' (Site from System).		14 Aug 2020 15:13:39
User entered missing code ND - Not Done; reason for change Data Entry Error		14 Aug 2020 01:58:20
Query 'Data is required. Please provide.' answered with 'Not done' (Site from System).		12 Aug 2020 17:21:11
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 17:20:35
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 17:20:35

US3292127
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered 'mmHg'	System	14 Aug 2020 01:58:20
User entered empty.	System	12 Aug 2020 17:20:35

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34

US3292127
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 16:21:43

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:28:35
User entered 'Yes (Y)'		12 Aug 2020 17:21:29

US3292127

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:21:43

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 08:28:51
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:28:35
User entered '11 Aug 2020'		12 Aug 2020 17:21:29

US3292127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:43

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 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:28:46
User entered 'No (N)'		12 Aug 2020 17:22:08

US3292127
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:21:43
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 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:28:46
User entered 'No (N)'		12 Aug 2020 17:22:08

US3292127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:43

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 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:28:46
User entered 'No (N)'		12 Aug 2020 17:22:08

US3292127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:43

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 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:28:46
User entered 'No (N)'		12 Aug 2020 17:22:08

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Form: Risk of Exposure

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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 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:28:46
User entered 'No (N)'		12 Aug 2020 17:22:08

US3292127
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:21:43
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 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:28:46
User entered 'No (N)'		12 Aug 2020 17:22:08

US3292127
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:21:43
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 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:28:46
User entered 'No (N)'		12 Aug 2020 17:22:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:43

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 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:28:46
User entered 'No (N)'		12 Aug 2020 17:22:08

US3292127
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:21:43
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 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:28:46
User entered 'No (N)'		12 Aug 2020 17:22:08

US3292127
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:21:43
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 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:28:46
User entered 'No (N)'		12 Aug 2020 17:22:08

US3292127
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:21:43
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 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:28:46
User entered 'No (N)'		12 Aug 2020 17:22:08

US3292127
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:21:43
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:28:46
User entered 'No (N)'		12 Aug 2020 17:22:08

US3292127
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:21:43
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:28:46
User entered empty.		12 Aug 2020 17:22:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:43

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:22:08

US3292127
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:21:43
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:28:46
User entered '0'		12 Aug 2020 17:22:08

US3292127
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:21:43
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 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:28:46
User entered '0'		12 Aug 2020 17:22:08

US3292127
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:21:43
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 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:28:46
User entered '0'		12 Aug 2020 17:22:08

US3292127
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:21:43
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 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:28:46
User entered '0'		12 Aug 2020 17:22:08

US3292127
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:21:43
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:28:46
User entered '1'		12 Aug 2020 17:22:08

US3292127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:21:43

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '0'	(b) (4), (b) (6)	12 Aug 2020 17:22:08

US3292127
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:21:43
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:28:46
User entered empty.		12 Aug 2020 17:22:08

US3292127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:21:43

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:28:57
User entered 'Yes (Y)'		12 Aug 2020 17:32:03

US3292127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:21:43

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:28:57
User entered '11 Aug 2020'	(b) (4), (b) (6)	12 Aug 2020 17:32:03

US3292127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:28:57
User entered 'Clinic (Clinic)'		12 Aug 2020 17:32:03

US3292127
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:21:43
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'VISIT1'	System	12 Aug 2020 17:32:03

US3292127
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:29:18
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 18:45:22

US3292127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:21:43

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:29:18
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:37:29
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:37:29
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 18:45:22
User entered '185729' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 18:45:22

US3292127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:21:43

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:29:18
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 18:45:22

US3292127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:21:43

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:29:18
User entered 'No (N)'		12 Aug 2020 17:32:59

US3292127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:21:43

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:29:18
User entered 'No (N)'		12 Aug 2020 17:32:59

US3292127
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:29:18
User entered 'No (N)'		12 Aug 2020 17:32:59

US3292127
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:21:43

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:29:18
User entered 'No (N)'		12 Aug 2020 17:32:59

US3292127
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:21:43

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:29:18
User entered 'No (N)'		12 Aug 2020 17:32:59

US3292127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:21:43

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:17:45
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:33:23

US3292127
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:21:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:12
User entered missing code ND - Not Done; reason for change Data Entry Error		14 Aug 2020 01:58:47
User entered empty.		12 Aug 2020 17:34:03

US3292127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:21:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:31:12
User entered missing code ND - Not Done; reason for change Data Entry Error		14 Aug 2020 01:58:47
User entered empty.		12 Aug 2020 17:34:03

US3292127
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:21:43
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:12
User entered missing code ND - Not Done; reason for change Data Entry Error		14 Aug 2020 01:58:47
User entered empty.		12 Aug 2020 17:34:03

US3292127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:21:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:31:12
User entered missing code ND - Not Done; reason fo change Data Entry Error		14 Aug 2020 01:58:47
User entered empty.		12 Aug 2020 17:34:03

US3292127
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:21:43
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User accepted default value 'Pre-Dose (PREDOSE)'		2 Aug 2020 17:34:03

US3292127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:31:12
User entered 'Yes (Y)'		12 Aug 2020 17:34:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:12
User entered '11 Aug 2020'		12 Aug 2020 17:34:03

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:12
User entered '13:00'		12 Aug 2020 17:34:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered '11 Aug 2020 13:00'	System	12 Aug 2020 17:34:03

US3292127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:31:12
User entered '36.6' C		12 Aug 2020 17:34:03

US3292127
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:21:43
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:31:12
User entered 'Oral (Oral)'		12 Aug 2020 17:34:03

US3292127
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:21:43
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:12
User entered empty.		12 Aug 2020 17:34:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:12
User entered '69'		12 Aug 2020 17:34:03

US3292127
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:21:43
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'bpm'	System	12 Aug 2020 17:34:03

US3292127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:31:12
User entered '16'		12 Aug 2020 17:34:03

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'breaths/min'	System	12 Aug 2020 17:34:03

US3292127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:31:12
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		14 Aug 2020 15:05:44
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Investigator indicates NCS on source' (Site from System).		12 Aug 2020 17:37:53
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	12 Aug 2020 17:34:03
User entered '160'	(b) (4), (b) (6)	12 Aug 2020 17:34:03

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'mmHg'	System	12 Aug 2020 17:34:03

US3292127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:31:12
User entered '84'		12 Aug 2020 17:34:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'mmHg'	System	12 Aug 2020 17:34:03

US3292127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:21:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:31:12
User entered missing code ND - Not Done; reason for change Data Entry Error		14 Aug 2020 01:58:47
User entered empty.		12 Aug 2020 17:34:03

US3292127
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:21:43
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:12
User entered missing code ND - Not Done; reason fo change Data Entry Error		14 Aug 2020 01:58:47
User entered empty.		12 Aug 2020 17:34:03

US3292127
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:21:43
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User accepted default value 'Post-Dose (POSTDOSE)'		2 Aug 2020 17:39:28

US3292127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:12
User entered 'Yes (Y)'		12 Aug 2020 17:39:28

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:21:43
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:12
User entered '11 Aug 2020'		12 Aug 2020 17:39:28

US3292127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:31:12
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 15:04:19
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'As per protocol, post dose vitals can be completed 30 minutes after dosing.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 17:40:37
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	12 Aug 2020 17:39:28
User entered '14:40'	(b) (4), (b) (6)	12 Aug 2020 17:39:28

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered '11 Aug 2020 14:40'	System	12 Aug 2020 17:39:28

US3292127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:12
User entered '36.3' C		12 Aug 2020 17:39:28

US3292127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:12
User entered 'Oral (Oral)'		12 Aug 2020 17:39:28

US3292127
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:21:43
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:31:12
User entered empty.		12 Aug 2020 17:39:28

US3292127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:12
User entered '74'		12 Aug 2020 17:39:28

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'bpm'	System	12 Aug 2020 17:39:28

US3292127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:31:12
User entered '16'		12 Aug 2020 17:39:28

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'breaths/min'	System	12 Aug 2020 17:39:28

US3292127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:31:12
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		18 Aug 2020 13:32:23
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS are per pi' (Site from System).		17 Aug 2020 18:37:04
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	12 Aug 2020 17:39:28
User entered '187'	(b) (4), (b) (6)	12 Aug 2020 17:39:28

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'mmHg'	System	12 Aug 2020 17:39:28

US3292127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:31:12
User entered '99'		12 Aug 2020 17:39:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'mmHg'	System	12 Aug 2020 17:39:28

US3292127
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 16:21:43
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:31:20
User entered 'No (N)' reason for change: Data Entry Error		14 Aug 2020 01:58:37
User entered 'Yes (Y)'		12 Aug 2020 17:41:52

US3292127
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 16:21:43
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:20
User entered empty; reason for change Data Entry Error		14 Aug 2020 01:58:37
User entered '11 Aug 2020'		12 Aug 2020 17:41:52

US3292127
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:21:43

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:31:37
User entered 'Yes (Y)'		11 Aug 2020 19:15:27

US3292127
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:21:43
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:31:37
User entered empty.		11 Aug 2020 19:15:27

US3292127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:31:37
User entered empty.		11 Aug 2020 19:15:27

US3292127
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:21:43
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 19:15:27

US3292127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:37
User entered '11 Aug 2020'		11 Aug 2020 19:15:27

US3292127
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:37
User entered '14:06'		11 Aug 2020 19:15:27

US3292127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:21:43

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered '11 Aug 2020 14:06'	System	11 Aug 2020 19:15:27

US3292127
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:21:43
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:37
User entered 'Left Arm (LEFT ARM)'		11 Aug 2020 19:15:27

US3292127
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:21:43

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
DataPoint Verified.		27 Aug 2020 17:31:37
User entered 'ONCE'	System	11 Aug 2020 19:15:27

US3292127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:21:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 19:15:27

US3292127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:43

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:31:45
User entered 'Yes (Y)'		12 Aug 2020 17:42:36

US3292127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:43

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:31:45
User entered '11 Aug 2020'		12 Aug 2020 17:42:36

US3292127
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:21:43
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:31:45
User entered '13:09'		12 Aug 2020 17:42:36

US3292127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:43

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered '11 Aug 2020 13:09'	System	12 Aug 2020 17:42:36

US3292127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:21:43

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:32:03
User entered '11 Aug 2020'		12 Aug 2020 17:43:11

US3292127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:21:43

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		12 Aug 2020 17:43:11

US3292127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:21:43

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:32:03
User entered 'Yes (Y)'		12 Aug 2020 17:43:11

US3292127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:32:03
User entered '13:28'		12 Aug 2020 17:43:11

Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:21:43
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered '11 Aug 2020 13:28'	System	12 Aug 2020 17:43:11

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		12 Aug 2020 17:43:21

US3292127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:21:43

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:32:03
User entered 'No (N)'		12 Aug 2020 17:43:21

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:32:03
User entered empty.		12 Aug 2020 17:43:21

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered empty.	System	12 Aug 2020 17:43:21

US3292127

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:33:16
User entered 'Yes (Y)'		12 Aug 2020 17:44:10

US3292127
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 16:21:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered '1'	System	12 Aug 2020 17:44:10

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:21:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T14:42:49', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5e6601cf-4b17-4534-8107-ae9090cdb872'	System	11 Aug 2020 19:43:41
User entered 'Yes (Y)'	System	11 Aug 2020 19:43:41

US3292127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T14:43:20', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5e6601cf-4b17-4534-8107-ae9090cdb872'	System	11 Aug 2020 19:43:41
User entered '97.4'	System	11 Aug 2020 19:43:41

US3292127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T14:43:29', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5e6601cf-4b17-4534-8107-ae9090cdb872'	System	11 Aug 2020 19:43:41
User entered 'No (N)'	System	11 Aug 2020 19:43:41

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T14:43:38', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5e6601cf-4b17-4534-8107-ae9090cdb872'	System	11 Aug 2020 19:43:41
User entered '11 Aug 2020 14:43'	System	11 Aug 2020 19:43:41

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:21:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '11 Aug 2020 14:26'	System	11 Aug 2020 19:15:27

US3292127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '11 Aug 2020 16:56'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:15:27

US3292127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:21:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T18:25:12', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '62c9bb53-cf20-4139-a8ed-8685c5bd65d7'	System	11 Aug 2020 23:26:12
User entered 'Yes (Y)'	System	11 Aug 2020 23:26:12

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:21:43

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T18:25:26', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '62c9bb53-cf20-4139-a8ed-8685c5bd65d7'	System	11 Aug 2020 23:26:12
User entered '98.8'	System	11 Aug 2020 23:26:12

US3292127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T18:25:47', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '62c9bb53-cf20-4139-a8ed-8685c5bd65d7'	System	11 Aug 2020 23:26:12
User entered 'No (N)'	System	11 Aug 2020 23:26:12

US3292127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:21:43

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T18:26:08', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '62c9bb53-cf20-4139-a8ed-8685c5bd65d7'	System	11 Aug 2020 23:26:12
User entered '11 Aug 2020 18:26'	System	11 Aug 2020 23:26:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '11 Aug 2020 17:51'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:21:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 2'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:21:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-12T18:34:25', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '0ed50ab5-baae-4d86-8f68-49d8892d14e6'	System	12 Aug 2020 23:35:12
User entered 'Yes (Y)'	System	12 Aug 2020 23:35:12

US3292127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:21:43

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-12T18:34:42', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '0ed50ab5-baae-4d86-8f68-49d8892d14e6'	System	12 Aug 2020 23:35:12
User entered '98.7'	System	12 Aug 2020 23:35:12

US3292127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-12T18:34:54', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '0ed50ab5-baae-4d86-8f68-49d8892d14e6'	System	12 Aug 2020 23:35:12
User entered 'No (N)'	System	12 Aug 2020 23:35:12

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:21:43

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-12T18:35:08', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '0ed50ab5-baae-4d86-8f68-49d8892d14e6'	System	12 Aug 2020 23:35:12
User entered '12 Aug 2020 18:35'	System	12 Aug 2020 23:35:12

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 3'	System	11 Aug 2020 19:15:27

US3292127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:21:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-13T18:32:59', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '6b5c9a3d-6b34-4700-b74c-207b70bf0cb5'	System	13 Aug 2020 23:33:25
User entered 'Yes (Y)'	System	13 Aug 2020 23:33:25

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:21:43

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-13T18:33:09', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '6b5c9a3d-6b34-4700-b74c-207b70bf0cb5'	System	13 Aug 2020 23:33:25
User entered '98.5'	System	13 Aug 2020 23:33:25

US3292127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-13T18:33:16', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '6b5c9a3d-6b34-4700-b74c-207b70bf0cb5'	System	13 Aug 2020 23:33:25
User entered 'No (N)'	System	13 Aug 2020 23:33:25

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:21:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-13T18:33:22', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '6b5c9a3d-6b34-4700-b74c-207b70bf0cb5'	System	13 Aug 2020 23:33:25
User entered '13 Aug 2020 18:33'	System	13 Aug 2020 23:33:25

US3292127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:21:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 4'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:21:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-14T18:35:22', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'c7dab1ab-2a63-49e1-bad4-4f5519bdb974'	System	14 Aug 2020 23:35:50
User entered 'Yes (Y)'	System	14 Aug 2020 23:35:50

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:21:43
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-14T18:35:30', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'c7dab1ab-2a63-49e1-bad4-4f5519bdb974'	System	14 Aug 2020 23:35:50
User entered '98.3'	System	14 Aug 2020 23:35:50

US3292127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-14T18:35:38', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'c7dab1ab-2a63-49e1-bad4-4f5519bdb974'	System	14 Aug 2020 23:35:50
User entered 'No (N)'	System	14 Aug 2020 23:35:50

US3292127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:21:43

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-14T18:35:46', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'c7dab1ab-2a63-49e1-bad4-4f5519bdb974'	System	14 Aug 2020 23:35:50
User entered '14 Aug 2020 18:35'	System	14 Aug 2020 23:35:50

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:15:27

US3292127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:21:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 5'	System	11 Aug 2020 19:15:27

US3292127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:21:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-15T18:36:11', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '59b61500-aaff-4316-9d96-63def0c45589'	System	15 Aug 2020 23:36:36
User entered 'Yes (Y)'	System	15 Aug 2020 23:36:36

US3292127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:21:43

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-15T18:36:21', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '59b61500-aaff-4316-9d96-63def0c45589'	System	15 Aug 2020 23:36:36
User entered '98.4'	System	15 Aug 2020 23:36:36

US3292127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-15T18:36:26', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '59b61500-aaff-4316-9d96-63def0c45589'	System	15 Aug 2020 23:36:36
User entered 'No (N)'	System	15 Aug 2020 23:36:36

US3292127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:21:43

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-15T18:36:31', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '59b61500-aaff-4316-9d96-63def0c45589'	System	15 Aug 2020 23:36:36
User entered '15 Aug 2020 18:36'	System	15 Aug 2020 23:36:36

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 6'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:21:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-16T18:31:03', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '815bc28c-1bac-44b8-8fed-383f8debeab2'	System	16 Aug 2020 23:31:23
User entered 'Yes (Y)'	System	16 Aug 2020 23:31:23

US3292127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:21:43

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-16T18:31:10', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '815bc28c-1bac-44b8-8fed-383f8debeab2'	System	16 Aug 2020 23:31:23
User entered '98.5'	System	16 Aug 2020 23:31:23

US3292127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-16T18:31:16', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '815bc28c-1bac-44b8-8fed-383f8debeab2'	System	16 Aug 2020 23:31:23
User entered 'No (N)'	System	16 Aug 2020 23:31:23

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:21:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-16T18:31:21', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '815bc28c-1bac-44b8-8fed-383f8debeab2'	System	16 Aug 2020 23:31:23
User entered '16 Aug 2020 18:31'	System	16 Aug 2020 23:31:23

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 7'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:21:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-17T18:27:52', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '2d6cb701-9948-4b0f-95e8-9af09d537efd'	System	17 Aug 2020 23:28:18
User entered 'Yes (Y)'	System	17 Aug 2020 23:28:18

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:21:43

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-17T18:28:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '2d6cb701-9948-4b0f-95e8-9af09d537efd'	System	17 Aug 2020 23:28:18
User entered '98.3'	System	17 Aug 2020 23:28:18

US3292127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-17T18:28:04', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '2d6cb701-9948-4b0f-95e8-9af09d537efd'	System	17 Aug 2020 23:28:18
User entered 'No (N)'	System	17 Aug 2020 23:28:18

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:21:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-17T18:28:13', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '2d6cb701-9948-4b0f-95e8-9af09d537efd'	System	17 Aug 2020 23:28:18
User entered '17 Aug 2020 18:28'	System	17 Aug 2020 23:28:18

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:21:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:15:27

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T14:44:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'd5c5c30c-f919-4a53-a1fc-833a942ad9a3'	System	11 Aug 2020 19:44:28
User entered 'None (1)'	System	11 Aug 2020 19:44:28

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T14:44:03', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'd5c5c30c-f919-4a53-a1fc-833a942ad9a3'	System	11 Aug 2020 19:44:28
User entered 'No (N)'	System	11 Aug 2020 19:44:28

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T14:44:08', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'd5c5c30c-f919-4a53-a1fc-833a942ad9a3'	System	11 Aug 2020 19:44:28
User entered 'No (N)'	System	11 Aug 2020 19:44:28

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T14:44:18', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'd5c5c30c-f919-4a53-a1fc-833a942ad9a3'	System	11 Aug 2020 19:44:28
User entered 'None (1)'	System	11 Aug 2020 19:44:28

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T14:44:25', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'd5c5c30c-f919-4a53-a1fc-833a942ad9a3'	System	11 Aug 2020 19:44:28
User entered '11 Aug 2020 14:44'	System	11 Aug 2020 19:44:28

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '11 Aug 2020 14:26'	System	11 Aug 2020 19:15:27

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '11 Aug 2020 16:56'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:15:27

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:21:43

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T18:26:40', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'c69d4da2-2267-465a-876b-720317129d0d'	System	11 Aug 2020 23:28:34
User entered 'None (1)'	System	11 Aug 2020 23:28:34

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T18:26:55', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'c69d4da2-2267-465a-876b-720317129d0d'	System	11 Aug 2020 23:28:34
User entered 'No (N)'	System	11 Aug 2020 23:28:34

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T18:27:15', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'c69d4da2-2267-465a-876b-720317129d0d'	System	11 Aug 2020 23:28:34
User entered 'No (N)'	System	11 Aug 2020 23:28:34

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T18:28:06', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'c69d4da2-2267-465a-876b-720317129d0d'	System	11 Aug 2020 23:28:34
User entered 'None (1)'	System	11 Aug 2020 23:28:34

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:21:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T18:28:28', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'c69d4da2-2267-465a-876b-720317129d0d'	System	11 Aug 2020 23:28:34
User entered '11 Aug 2020 18:28'	System	11 Aug 2020 23:28:34

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '11 Aug 2020 17:51'	System	11 Aug 2020 19:15:27

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 2'	System	11 Aug 2020 19:15:27

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-12T18:35:25', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'db71ccda-daee-4677-99d2-74a92387fd71'	System	12 Aug 2020 23:36:52
User entered 'None (1)'	System	12 Aug 2020 23:36:52

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-12T18:35:51', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'db71ccda-daee-4677-99d2-74a92387fd71'	System	12 Aug 2020 23:36:52
User entered 'No (N)'	System	12 Aug 2020 23:36:52

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-12T18:36:03', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'db71ccda-daee-4677-99d2-74a92387fd71'	System	12 Aug 2020 23:36:52
User entered 'No (N)'	System	12 Aug 2020 23:36:52

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-12T18:36:30', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'db71ccda-daee-4677-99d2-74a92387fd71'	System	12 Aug 2020 23:36:52
User entered 'None (1)'	System	12 Aug 2020 23:36:52

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:21:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-12T18:36:50', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'db71ccda-daee-4677-99d2-74a92387fd71'	System	12 Aug 2020 23:36:52
User entered '12 Aug 2020 18:36'	System	12 Aug 2020 23:36:52

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 3'	System	11 Aug 2020 19:15:27

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-13T18:33:31', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'eafdf21c-0642-4795-9d26-78cffc10623d'	System	13 Aug 2020 23:34:00
User entered 'None (1)'	System	13 Aug 2020 23:34:00

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-13T18:33:36', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'eafdf21c-0642-4795-9d26-78cffc10623d'	System	13 Aug 2020 23:34:00
User entered 'No (N)'	System	13 Aug 2020 23:34:00

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-13T18:33:40', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'eafdf21c-0642-4795-9d26-78cffc10623d'	System	13 Aug 2020 23:34:00
User entered 'No (N)'	System	13 Aug 2020 23:34:00

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-13T18:33:46', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'eafdf21c-0642-4795-9d26-78cffc10623d'	System	13 Aug 2020 23:34:00
User entered 'None (1)'	System	13 Aug 2020 23:34:00

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:21:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-13T18:33:56', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'eafdf21c-0642-4795-9d26-78cffc10623d'	System	13 Aug 2020 23:34:00
User entered '13 Aug 2020 18:33'	System	13 Aug 2020 23:34:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 4'	System	11 Aug 2020 19:15:27

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:21:43

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-14T18:36:07', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'cf192fc8-8bc5-49d5-822e-fddd1fb5e560'	System	14 Aug 2020 23:36:34
User entered 'None (1)'	System	14 Aug 2020 23:36:34

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-14T18:36:12', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'cf192fc8-8bc5-49d5-822e-fddd1fb5e560'	System	14 Aug 2020 23:36:34
User entered 'No (N)'	System	14 Aug 2020 23:36:34

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-14T18:36:17', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'cf192fc8-8bc5-49d5-822e-fddd1fb5e560'	System	14 Aug 2020 23:36:34
User entered 'No (N)'	System	14 Aug 2020 23:36:34

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-14T18:36:23', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'cf192fc8-8bc5-49d5-822e-fddd1fb5e560'	System	14 Aug 2020 23:36:34
User entered 'None (1)'	System	14 Aug 2020 23:36:34

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:21:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-14T18:36:32', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'cf192fc8-8bc5-49d5-822e-fddd1fb5e560'	System	14 Aug 2020 23:36:34
User entered '14 Aug 2020 18:36'	System	14 Aug 2020 23:36:34

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:15:27

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 5'	System	11 Aug 2020 19:15:27

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-15T18:36:39', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '85e3ab8c-0100-4839-a6b4-cae4c9816b5c'	System	15 Aug 2020 23:37:09
User entered 'None (1)'	System	15 Aug 2020 23:37:09

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-15T18:36:44', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '85e3ab8c-0100-4839-a6b4-cae4c9816b5c'	System	15 Aug 2020 23:37:09
User entered 'No (N)'	System	15 Aug 2020 23:37:09

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-15T18:36:49', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '85e3ab8c-0100-4839-a6b4-cae4c9816b5c'	System	15 Aug 2020 23:37:09
User entered 'No (N)'	System	15 Aug 2020 23:37:09

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-15T18:36:59', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '85e3ab8c-0100-4839-a6b4-cae4c9816b5c'	System	15 Aug 2020 23:37:09
User entered 'None (1)'	System	15 Aug 2020 23:37:09

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:21:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-15T18:37:06', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '85e3ab8c-0100-4839-a6b4-cae4c9816b5c'	System	15 Aug 2020 23:37:09
User entered '15 Aug 2020 18:37'	System	15 Aug 2020 23:37:09

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 6'	System	11 Aug 2020 19:15:27

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:21:43

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-16T18:31:32', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'aa7b6185-0cbf-4f37-9203-0db4e3c2a350'	System	16 Aug 2020 23:32:03
User entered 'None (1)'	System	16 Aug 2020 23:32:03

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-16T18:31:36', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'aa7b6185-0cbf-4f37-9203-0db4e3c2a350'	System	16 Aug 2020 23:32:03
User entered 'No (N)'	System	16 Aug 2020 23:32:03

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-16T18:31:42', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'aa7b6185-0cbf-4f37-9203-0db4e3c2a350'	System	16 Aug 2020 23:32:03
User entered 'No (N)'	System	16 Aug 2020 23:32:03

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-16T18:31:47', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'aa7b6185-0cbf-4f37-9203-0db4e3c2a350'	System	16 Aug 2020 23:32:03
User entered 'None (1)'	System	16 Aug 2020 23:32:03

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:21:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-16T18:31:57', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'aa7b6185-0cbf-4f37-9203-0db4e3c2a350'	System	16 Aug 2020 23:32:03
User entered '16 Aug 2020 18:31'	System	16 Aug 2020 23:32:03

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 7'	System	11 Aug 2020 19:15:27

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-17T18:28:20', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'f5af9dca-4906-440d-a3d3-a68dd99675b5'	System	17 Aug 2020 23:28:40
User entered 'None (1)'	System	17 Aug 2020 23:28:40

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-17T18:28:25', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'f5af9dca-4906-440d-a3d3-a68dd99675b5'	System	17 Aug 2020 23:28:40
User entered 'No (N)'	System	17 Aug 2020 23:28:40

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-17T18:28:29', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'f5af9dca-4906-440d-a3d3-a68dd99675b5'	System	17 Aug 2020 23:28:40
User entered 'No (N)'	System	17 Aug 2020 23:28:40

US3292127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:21:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-17T18:28:33', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'f5af9dca-4906-440d-a3d3-a68dd99675b5'	System	17 Aug 2020 23:28:40
User entered 'None (1)'	System	17 Aug 2020 23:28:40

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:21:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-17T18:28:38', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'f5af9dca-4906-440d-a3d3-a68dd99675b5'	System	17 Aug 2020 23:28:40
User entered '17 Aug 2020 18:28'	System	17 Aug 2020 23:28:40

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T14:44:35', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'd34ec2d1-58fa-4868-8088-2fb025ee3c4f'	System	11 Aug 2020 19:45:23
User entered 'None (0)'	System	11 Aug 2020 19:45:23

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T14:44:41', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'd34ec2d1-58fa-4868-8088-2fb025ee3c4f'	System	11 Aug 2020 19:45:23
User entered 'None (0)'	System	11 Aug 2020 19:45:23

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T14:44:46', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'd34ec2d1-58fa-4868-8088-2fb025ee3c4f'	System	11 Aug 2020 19:45:23
User entered 'None (0)'	System	11 Aug 2020 19:45:23

US3292127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T14:44:53', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'd34ec2d1-58fa-4868-8088-2fb025ee3c4f'	System	11 Aug 2020 19:45:23
User entered 'None (0)'	System	11 Aug 2020 19:45:23

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T14:44:59', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'd34ec2d1-58fa-4868-8088-2fb025ee3c4f'	System	11 Aug 2020 19:45:23
User entered 'None (0)'	System	11 Aug 2020 19:45:23

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T14:45:04', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'd34ec2d1-58fa-4868-8088-2fb025ee3c4f'	System	11 Aug 2020 19:45:23
User entered 'None (0)'	System	11 Aug 2020 19:45:23

US3292127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

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)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T14:45:13', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'd34ec2d1-58fa-4868-8088-2fb025ee3c4f'	System	11 Aug 2020 19:45:23
User entered 'No (N)'	System	11 Aug 2020 19:45:23

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T14:45:21', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'd34ec2d1-58fa-4868-8088-2fb025ee3c4f'	System	11 Aug 2020 19:45:23
User entered '11 Aug 2020 14:45'	System	11 Aug 2020 19:45:23

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '11 Aug 2020 14:26'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '11 Aug 2020 16:56'	System	11 Aug 2020 19:15:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:21:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T18:29:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '8cce3179-4e00-46ab-bced-76f77aa3d667'	System	11 Aug 2020 23:31:20
User entered 'None (0)'	System	11 Aug 2020 23:31:20

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:21:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T18:29:13', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '8cce3179-4e00-46ab-bced-76f77aa3d667'	System	11 Aug 2020 23:31:20
User entered 'None (0)'	System	11 Aug 2020 23:31:20

US3292127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T18:29:34', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '8cce3179-4e00-46ab-bced-76f77aa3d667'	System	11 Aug 2020 23:31:20
User entered 'None (0)'	System	11 Aug 2020 23:31:20

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:21:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T18:29:46', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '8cce3179-4e00-46ab-bced-76f77aa3d667'	System	11 Aug 2020 23:31:20
User entered 'None (0)'	System	11 Aug 2020 23:31:20

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:21:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T18:30:04', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '8cce3179-4e00-46ab-bced-76f77aa3d667'	System	11 Aug 2020 23:31:20
User entered 'None (0)'	System	11 Aug 2020 23:31:20

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:21:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T18:30:22', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '8cce3179-4e00-46ab-bced-76f77aa3d667'	System	11 Aug 2020 23:31:20
User entered 'None (0)'	System	11 Aug 2020 23:31:20

US3292127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:21:43

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)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T18:30:43', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '8cce3179-4e00-46ab-bced-76f77aa3d667'	System	11 Aug 2020 23:31:20
User entered 'No (N)'	System	11 Aug 2020 23:31:20

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:21:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-11T18:31:16', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '8cce3179-4e00-46ab-bced-76f77aa3d667'	System	11 Aug 2020 23:31:20
User entered '11 Aug 2020 18:31'	System	11 Aug 2020 23:31:20

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:21:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '11 Aug 2020 17:51'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 2'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:21:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-12T18:37:04', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '40271bcb-d1d1-41b7-995a-043f1272d63b'	System	12 Aug 2020 23:38:36
User entered 'None (0)'	System	12 Aug 2020 23:38:36

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:21:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-12T18:37:12', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '40271bcb-d1d1-41b7-995a-043f1272d63b'	System	12 Aug 2020 23:38:36
User entered 'None (0)'	System	12 Aug 2020 23:38:36

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:21:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-12T18:37:20', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '40271bcb-d1d1-41b7-995a-043f1272d63b'	System	12 Aug 2020 23:38:36
User entered 'None (0)'	System	12 Aug 2020 23:38:36

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:21:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-12T18:37:28', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '40271bcb-d1d1-41b7-995a-043f1272d63b'	System	12 Aug 2020 23:38:36
User entered 'None (0)'	System	12 Aug 2020 23:38:36

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:21:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-12T18:37:44', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '40271bcb-d1d1-41b7-995a-043f1272d63b'	System	12 Aug 2020 23:38:36
User entered 'None (0)'	System	12 Aug 2020 23:38:36

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:21:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-12T18:37:57', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '40271bcb-d1d1-41b7-995a-043f1272d63b'	System	12 Aug 2020 23:38:36
User entered 'None (0)'	System	12 Aug 2020 23:38:36

US3292127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:43

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)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-12T18:38:11', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '40271bcb-d1d1-41b7-995a-043f1272d63b'	System	12 Aug 2020 23:38:36
User entered 'No (N)'	System	12 Aug 2020 23:38:36

US3292127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:43

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-12T18:38:33', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '40271bcb-d1d1-41b7-995a-043f1272d63b'	System	12 Aug 2020 23:38:36
User entered '12 Aug 2020 18:38'	System	12 Aug 2020 23:38:36

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:21:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 3'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:21:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-13T18:34:03', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '393c0625-16e5-4f0d-af77-228429a3b691'	System	13 Aug 2020 23:34:50
User entered 'None (0)'	System	13 Aug 2020 23:34:50

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:21:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-13T18:34:07', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '393c0625-16e5-4f0d-af77-228429a3b691'	System	13 Aug 2020 23:34:50
User entered 'None (0)'	System	13 Aug 2020 23:34:50

US3292127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-13T18:34:11', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '393c0625-16e5-4f0d-af77-228429a3b691'	System	13 Aug 2020 23:34:50
User entered 'None (0)'	System	13 Aug 2020 23:34:50

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:21:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-13T18:34:15', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '393c0625-16e5-4f0d-af77-228429a3b691'	System	13 Aug 2020 23:34:50
User entered 'None (0)'	System	13 Aug 2020 23:34:50

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:21:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-13T18:34:18', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '393c0625-16e5-4f0d-af77-228429a3b691'	System	13 Aug 2020 23:34:50
User entered 'None (0)'	System	13 Aug 2020 23:34:50

US3292127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-13T18:34:25', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '393c0625-16e5-4f0d-af77-228429a3b691'	System	13 Aug 2020 23:34:50
User entered 'None (0)'	System	13 Aug 2020 23:34:50

US3292127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:43

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)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-13T18:34:36', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '393c0625-16e5-4f0d-af77-228429a3b691'	System	13 Aug 2020 23:34:50
User entered 'No (N)'	System	13 Aug 2020 23:34:50

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:21:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-13T18:34:49', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '393c0625-16e5-4f0d-af77-228429a3b691'	System	13 Aug 2020 23:34:50
User entered '13 Aug 2020 18:34'	System	13 Aug 2020 23:34:50

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:15:27

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 4'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:21:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-14T18:36:40', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '8b131b84-da7f-4a41-8d18-4e602dfbd3d9'	System	14 Aug 2020 23:37:19
User entered 'None (0)'	System	14 Aug 2020 23:37:19

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:21:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-14T18:36:43', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '8b131b84-da7f-4a41-8d18-4e602dfbd3d9'	System	14 Aug 2020 23:37:19
User entered 'None (0)'	System	14 Aug 2020 23:37:19

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:21:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-14T18:36:46', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '8b131b84-da7f-4a41-8d18-4e602dfbd3d9'	System	14 Aug 2020 23:37:19
User entered 'None (0)'	System	14 Aug 2020 23:37:19

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:21:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-14T18:36:51', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '8b131b84-da7f-4a41-8d18-4e602dfbd3d9'	System	14 Aug 2020 23:37:19
User entered 'None (0)'	System	14 Aug 2020 23:37:19

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:21:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-14T18:36:54', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '8b131b84-da7f-4a41-8d18-4e602dfbd3d9'	System	14 Aug 2020 23:37:19
User entered 'None (0)'	System	14 Aug 2020 23:37:19

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:21:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-14T18:36:57', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '8b131b84-da7f-4a41-8d18-4e602dfbd3d9'	System	14 Aug 2020 23:37:19
User entered 'None (0)'	System	14 Aug 2020 23:37:19

US3292127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:43

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)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-14T18:37:06', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '8b131b84-da7f-4a41-8d18-4e602dfbd3d9'	System	14 Aug 2020 23:37:19
User entered 'No (N)'	System	14 Aug 2020 23:37:19

US3292127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:43

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-14T18:37:16', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '8b131b84-da7f-4a41-8d18-4e602dfbd3d9'	System	14 Aug 2020 23:37:19
User entered '14 Aug 2020 18:37'	System	14 Aug 2020 23:37:19

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:15:27

US3292127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 5'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:21:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-15T18:37:16', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '27721de0-d175-49e7-838c-daae9048d8ba'	System	15 Aug 2020 23:37:54
User entered 'None (0)'	System	15 Aug 2020 23:37:54

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:21:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-15T18:37:21', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '27721de0-d175-49e7-838c-daae9048d8ba'	System	15 Aug 2020 23:37:54
User entered 'None (0)'	System	15 Aug 2020 23:37:54

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:21:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-15T18:37:25', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '27721de0-d175-49e7-838c-daae9048d8ba'	System	15 Aug 2020 23:37:54
User entered 'None (0)'	System	15 Aug 2020 23:37:54

US3292127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-15T18:37:29', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '27721de0-d175-49e7-838c-daae9048d8ba'	System	15 Aug 2020 23:37:54
User entered 'None (0)'	System	15 Aug 2020 23:37:54

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:21:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-15T18:37:32', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '27721de0-d175-49e7-838c-daae9048d8ba'	System	15 Aug 2020 23:37:54
User entered 'None (0)'	System	15 Aug 2020 23:37:54

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:21:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-15T18:37:35', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '27721de0-d175-49e7-838c-daae9048d8ba'	System	15 Aug 2020 23:37:54
User entered 'None (0)'	System	15 Aug 2020 23:37:54

US3292127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:43

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)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-15T18:37:42', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '27721de0-d175-49e7-838c-daae9048d8ba'	System	15 Aug 2020 23:37:54
User entered 'No (N)'	System	15 Aug 2020 23:37:54

US3292127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:43

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-15T18:37:52', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '27721de0-d175-49e7-838c-daae9048d8ba'	System	15 Aug 2020 23:37:54
User entered '15 Aug 2020 18:37'	System	15 Aug 2020 23:37:54

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:21:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 6'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:21:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-16T18:32:05', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '31f731c6-41f4-471d-8538-413aa55f7a3d'	System	16 Aug 2020 23:32:42
User entered 'None (0)'	System	16 Aug 2020 23:32:42

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:21:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-16T18:32:09', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '31f731c6-41f4-471d-8538-413aa55f7a3d'	System	16 Aug 2020 23:32:42
User entered 'None (0)'	System	16 Aug 2020 23:32:42

US3292127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-16T18:32:12', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '31f731c6-41f4-471d-8538-413aa55f7a3d'	System	16 Aug 2020 23:32:42
User entered 'None (0)'	System	16 Aug 2020 23:32:42

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:21:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-16T18:32:15', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '31f731c6-41f4-471d-8538-413aa55f7a3d'	System	16 Aug 2020 23:32:42
User entered 'None (0)'	System	16 Aug 2020 23:32:42

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:21:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-16T18:32:18', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '31f731c6-41f4-471d-8538-413aa55f7a3d'	System	16 Aug 2020 23:32:42
User entered 'None (0)'	System	16 Aug 2020 23:32:42

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:21:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-16T18:32:22', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '31f731c6-41f4-471d-8538-413aa55f7a3d'	System	16 Aug 2020 23:32:42
User entered 'None (0)'	System	16 Aug 2020 23:32:42

US3292127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:43

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)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-16T18:32:28', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '31f731c6-41f4-471d-8538-413aa55f7a3d'	System	16 Aug 2020 23:32:42
User entered 'No (N)'	System	16 Aug 2020 23:32:42

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:21:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-16T18:32:40', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '31f731c6-41f4-471d-8538-413aa55f7a3d'	System	16 Aug 2020 23:32:42
User entered '16 Aug 2020 18:32'	System	16 Aug 2020 23:32:42

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 7'	System	11 Aug 2020 19:15:27

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:21:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-17T18:28:44', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'b232543d-b5d7-4e0d-83f4-447fac27e458'	System	17 Aug 2020 23:29:31
User entered 'None (0)'	System	17 Aug 2020 23:29:31

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:21:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-17T18:28:52', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'b232543d-b5d7-4e0d-83f4-447fac27e458'	System	17 Aug 2020 23:29:31
User entered 'None (0)'	System	17 Aug 2020 23:29:31

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:21:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-17T18:28:56', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'b232543d-b5d7-4e0d-83f4-447fac27e458'	System	17 Aug 2020 23:29:31
User entered 'None (0)'	System	17 Aug 2020 23:29:31

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:21:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-17T18:28:59', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'b232543d-b5d7-4e0d-83f4-447fac27e458'	System	17 Aug 2020 23:29:31
User entered 'None (0)'	System	17 Aug 2020 23:29:31

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:21:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-17T18:29:03', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'b232543d-b5d7-4e0d-83f4-447fac27e458'	System	17 Aug 2020 23:29:31
User entered 'None (0)'	System	17 Aug 2020 23:29:31

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:21:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-17T18:29:06', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'b232543d-b5d7-4e0d-83f4-447fac27e458'	System	17 Aug 2020 23:29:31
User entered 'None (0)'	System	17 Aug 2020 23:29:31

US3292127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:43

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)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-17T18:29:13', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'b232543d-b5d7-4e0d-83f4-447fac27e458'	System	17 Aug 2020 23:29:31
User entered 'No (N)'	System	17 Aug 2020 23:29:31

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:21:43

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-08-17T18:29:26', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'b232543d-b5d7-4e0d-83f4-447fac27e458'	System	17 Aug 2020 23:29:31
User entered '17 Aug 2020 18:29'	System	17 Aug 2020 23:29:31

US3292127
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:15:27

US3292127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:21:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:15:27

US3292127
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:42:27
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	19 Aug 2020 01:53:33

US3292127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:43

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:42:27
User entered '18 Aug 2020'	Dawn Killian (b) (4) (b) (4)	19 Aug 2020 01:53:33

US3292127
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:42:27
User entered 'Contact Made (CONTACT MADE)'	Dawn Killian (b) (4) (b) (4)	19 Aug 2020 01:53:33

US3292127
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:42:27
User entered empty.	Dawn Killian (b) (4) (b) (4)	19 Aug 2020 01:53:33

US3292127
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:42:33
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	19 Aug 2020 01:53:39

US3292127
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered '1'	System	19 Aug 2020 01:53:39

US3292127
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:43:06
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	26 Aug 2020 14:24:30

US3292127
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:43:06
User entered '26 Aug 2020'	Kristy Trevino (b) (4) (b) (4)	26 Aug 2020 14:24:30

US3292127
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:43:06
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4) (b) (4)	26 Aug 2020 14:24:30

US3292127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:43

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:43:06
User entered empty.	Kristy Trevino (b) (4) (b) (4)	26 Aug 2020 14:24:30

US3292127
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:43:10
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	26 Aug 2020 14:24:37

US3292127
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered '1'	System	26 Aug 2020 14:24:37

US3292127
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:43:24
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	02 Sep 2020 05:24:06

US3292127
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:43:24
User entered '1 Sep 2020'	Kristy Trevino (b) (4) (b) (4)	02 Sep 2020 05:24:06

US3292127
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:43:24
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4) (b) (4)	02 Sep 2020 05:24:06

US3292127
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:43:24
User entered empty.	Kristy Trevino (b) (4) (b) (4)	02 Sep 2020 05:24:06

US3292127

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:43:32
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	02 Sep 2020 05:24:11

US3292127
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered '1'	System	02 Sep 2020 05:24:11

US3292127
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:21:43

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:50:45
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 19:17:49

US3292127
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:21:43
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:50:45
User entered '8 Sep 2020'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 19:17:49

US3292127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:50:45
User entered 'Clinic (Clinic)'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 19:17:49

US3292127
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:21:43
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'VISIT2'	System	08 Sep 2020 19:17:49

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User accepted default value 'Pre-Dose (PREDOSE)'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 19:18:53

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:53:17
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 19:18:53

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:53:17
User entered '8 Sep 2020'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 19:18:53

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:53:17
User entered '11:38'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 19:18:53

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered '8 Sep 2020 11:38'	System	08 Sep 2020 19:18:53

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:53:17
User entered '36.6' C	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 19:18:53

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:53:17
User entered 'Oral (Oral)'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 19:18:53

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:53:17
User entered empty.	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 19:18:53

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:53:17
User entered '81'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 19:18:53

US3292127
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:21:43
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'bpm'	System	08 Sep 2020 19:18:53

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:53:17
User entered '16'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 19:18:53

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'breaths/min'	System	08 Sep 2020 19:18:53

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:53:17
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		16 Sep 2020 18:17:47
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per Investigator' (Site from System).	Kevin Martinez (b) (4) (b) (4)	08 Sep 2020 21:45:14
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	08 Sep 2020 19:18:53
User entered '157'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 19:18:53

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'mmHg'	System	08 Sep 2020 19:18:53

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:53:17
User entered '87'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 19:18:53

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'mmHg'	System	08 Sep 2020 19:18:53

US3292127
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:21:43
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User accepted default value 'Post-Dose (POSTDOSE)'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 20:28:41

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:53:17
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 20:28:41

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:53:17
User entered '8 Sep 2020'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 20:28:41

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:53:17
User entered '12:51'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 20:28:41

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered '8 Sep 2020 12:51'	System	08 Sep 2020 20:28:41

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:53:17
User entered '36.5' C	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 20:28:41

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:53:17
User entered 'Oral (Oral)'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 20:28:41

US3292127
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:21:43
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:53:17
User entered empty.	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 20:28:41

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:53:17
User entered '73'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 20:28:41

US3292127
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:21:43
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'bpm'	System	08 Sep 2020 20:28:41

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:53:17
User entered '16'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 20:28:41

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'breaths/min'	System	08 Sep 2020 20:28:41

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:53:17
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		16 Sep 2020 18:17:52
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per Investigator' (Site from System).	Kevin Martinez (b) (4) (b) (4)	08 Sep 2020 21:45:31
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	08 Sep 2020 20:28:41
User entered '166'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 20:28:41

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'mmHg'	System	08 Sep 2020 20:28:41

US3292127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:53:17
User entered '89'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 20:28:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'mmHg'	System	08 Sep 2020 20:28:41

US3292127

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:21:43

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:53:49
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 20:29:18

US3292127

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:21:43

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:53:49
User entered '8 Sep 2020'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 20:29:18

US3292127
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:21:43
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:54:47
User entered 'Yes (Y)'		08 Sep 2020 17:36:00

US3292127
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:21:43

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:54:47
User entered empty.		08 Sep 2020 17:36:00

US3292127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:54:47
User entered empty.		08 Sep 2020 17:36:00

US3292127
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:21:43
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 17:36:00

US3292127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:54:47
User entered '8 Sep 2020'		08 Sep 2020 17:36:00

US3292127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:54:47
User entered '12:21'		08 Sep 2020 17:36:00

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:21:43

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered '8 Sep 2020 12:21'	System	08 Sep 2020 17:36:00

US3292127
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:21:43
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:54:47
User entered 'Left Arm (LEFT ARM)'		08 Sep 2020 17:36:00

US3292127
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:21:43
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
DataPoint Verified.		13 Jan 2021 18:54:47
User entered 'ONCE'	System	08 Sep 2020 17:36:00

US3292127
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:21:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 17:36:00

US3292127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:43

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:55:01
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 20:29:45

US3292127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:43

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:55:01
User entered '8 Sep 2020'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 20:29:45

US3292127
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:21:43
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:55:01
User entered '11:43'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 20:29:45

US3292127
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:21:43
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered '8 Sep 2020 11:43'	System	08 Sep 2020 20:29:45

US3292127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:21:43

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:55:10
User entered '8 Sep 2020'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 20:30:08

US3292127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:21:43

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 20:30:08

US3292127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:21:43

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:55:10
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 20:30:08

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:55:10
User entered '11:55'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 20:30:08

US3292127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:21:43

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered '8 Sep 2020 11:55'	System	08 Sep 2020 20:30:08

US3292127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:21:43

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 20:30:08

US3292127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:21:43

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:55:10
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 20:30:08

US3292127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:55:10
User entered empty.	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 20:30:08

US3292127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:21:43

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered empty.	System	08 Sep 2020 20:30:08

US3292127

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:56:07
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	08 Sep 2020 20:30:16

US3292127
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered '1'	System	08 Sep 2020 20:30:16

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	08 Sep 2020 17:36:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 17:36:00

US3292127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-08T12:58:33', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'f8dc580a-bf26-4042-aa45-6973fdcf7c96'	System	08 Sep 2020 17:59:04
User entered 'Yes (Y)'	System	08 Sep 2020 17:59:04

US3292127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-08T12:58:43', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'f8dc580a-bf26-4042-aa45-6973fdcf7c96'	System	08 Sep 2020 17:59:04
User entered '97.7'	System	08 Sep 2020 17:59:04

US3292127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-08T12:58:49', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'f8dc580a-bf26-4042-aa45-6973fdcf7c96'	System	08 Sep 2020 17:59:04
User entered 'No (N)'	System	08 Sep 2020 17:59:04

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-08T12:59:02', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'f8dc580a-bf26-4042-aa45-6973fdcf7c96'	System	08 Sep 2020 17:59:04
User entered '08 Sep 2020 12:59'	System	08 Sep 2020 17:59:04

US3292127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '08 Sep 2020 12:41'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '08 Sep 2020 15:11'	System	08 Sep 2020 17:36:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	08 Sep 2020 17:36:00
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:21:43
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:21:43
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:21:43
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:21:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '08 Sep 2020 16:06'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	08 Sep 2020 17:36:00
User entered 'Day 2'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:21:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-09T12:48:27', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'a0df4c7d-a244-461b-afe4-68e684310195'	System	09 Sep 2020 17:48:53
User entered 'Yes (Y)'	System	09 Sep 2020 17:48:53

US3292127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:21:43

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-09T12:48:37', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'a0df4c7d-a244-461b-afe4-68e684310195'	System	09 Sep 2020 17:48:53
User entered '98.9'	System	09 Sep 2020 17:48:53

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-09T12:48:43', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'a0df4c7d-a244-461b-afe4-68e684310195'	System	09 Sep 2020 17:48:53
User entered 'No (N)'	System	09 Sep 2020 17:48:53

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:21:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-09T12:48:48', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'a0df4c7d-a244-461b-afe4-68e684310195'	System	09 Sep 2020 17:48:53
User entered '09 Sep 2020 12:48'	System	09 Sep 2020 17:48:53

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	08 Sep 2020 17:36:00
User entered 'Day 3'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:21:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-10T12:23:16', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '40218b06-54a6-4eff-99fa-b99275f93801'	System	10 Sep 2020 17:23:43
User entered 'Yes (Y)'	System	10 Sep 2020 17:23:43

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:21:43

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-10T12:23:28', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '40218b06-54a6-4eff-99fa-b99275f93801'	System	10 Sep 2020 17:23:43
User entered '97.6'	System	10 Sep 2020 17:23:43

US3292127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-10T12:23:32', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '40218b06-54a6-4eff-99fa-b99275f93801'	System	10 Sep 2020 17:23:43
User entered 'No (N)'	System	10 Sep 2020 17:23:43

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:21:43

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-10T12:23:41', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '40218b06-54a6-4eff-99fa-b99275f93801'	System	10 Sep 2020 17:23:43
User entered '10 Sep 2020 12:23'	System	10 Sep 2020 17:23:43

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	08 Sep 2020 17:36:00
User entered 'Day 4'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:21:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-11T18:29:34', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '744ac241-2904-437e-ae1a-0b05c073e842'	System	11 Sep 2020 23:30:10
User entered 'Yes (Y)'	System	11 Sep 2020 23:30:10

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:21:43

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-11T18:29:48', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '744ac241-2904-437e-ae1a-0b05c073e842'	System	11 Sep 2020 23:30:10
User entered '98.8'	System	11 Sep 2020 23:30:10

US3292127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-11T18:29:53', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '744ac241-2904-437e-ae1a-0b05c073e842'	System	11 Sep 2020 23:30:10
User entered 'No (N)'	System	11 Sep 2020 23:30:10

US3292127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:21:43

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-11T18:30:06', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '744ac241-2904-437e-ae1a-0b05c073e842'	System	11 Sep 2020 23:30:10
User entered '11 Sep 2020 18:30'	System	11 Sep 2020 23:30:10

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:21:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	08 Sep 2020 17:36:00
User entered 'Day 5'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:21:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-12T12:31:25', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'a5516bf7-54b8-4fcc-9235-1457e6f184dd'	System	12 Sep 2020 17:31:49
User entered 'Yes (Y)'	System	12 Sep 2020 17:31:49

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:21:43
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-12T12:31:34', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'a5516bf7-54b8-4fcc-9235-1457e6f184dd'	System	12 Sep 2020 17:31:49
User entered '98.5'	System	12 Sep 2020 17:31:49

US3292127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-12T12:31:38', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'a5516bf7-54b8-4fcc-9235-1457e6f184dd'	System	12 Sep 2020 17:31:49
User entered 'No (N)'	System	12 Sep 2020 17:31:49

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:21:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-12T12:31:44', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'a5516bf7-54b8-4fcc-9235-1457e6f184dd'	System	12 Sep 2020 17:31:49
User entered '12 Sep 2020 12:31'	System	12 Sep 2020 17:31:49

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 17:36:00

US3292127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:21:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	08 Sep 2020 17:36:00
User entered 'Day 6'	System	08 Sep 2020 17:36:00

US3292127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:21:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-13T12:27:45', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '58b1aac8-7b57-41b4-a057-f8b1e90e221c'	System	13 Sep 2020 17:28:17
User entered 'Yes (Y)'	System	13 Sep 2020 17:28:17

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:21:43

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-13T12:27:53', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '58b1aac8-7b57-41b4-a057-f8b1e90e221c'	System	13 Sep 2020 17:28:17
User entered '98.0'	System	13 Sep 2020 17:28:17

US3292127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-13T12:27:57', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '58b1aac8-7b57-41b4-a057-f8b1e90e221c'	System	13 Sep 2020 17:28:17
User entered 'No (N)'	System	13 Sep 2020 17:28:17

US3292127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:21:43

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-13T12:28:02', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '58b1aac8-7b57-41b4-a057-f8b1e90e221c'	System	13 Sep 2020 17:28:17
User entered '13 Sep 2020 12:28'	System	13 Sep 2020 17:28:17

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:21:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 17:36:00

US3292127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:21:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	08 Sep 2020 17:36:00
User entered 'Day 7'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:21:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-14T13:27:59', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5c452fe0-5887-4597-a9b3-fd82856656a9'	System	14 Sep 2020 18:28:20
User entered 'Yes (Y)'	System	14 Sep 2020 18:28:20

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:21:43

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-14T13:28:07', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5c452fe0-5887-4597-a9b3-fd82856656a9'	System	14 Sep 2020 18:28:20
User entered '98.7'	System	14 Sep 2020 18:28:20

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-14T13:28:12', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5c452fe0-5887-4597-a9b3-fd82856656a9'	System	14 Sep 2020 18:28:20
User entered 'No (N)'	System	14 Sep 2020 18:28:20

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:21:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-14T13:28:17', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5c452fe0-5887-4597-a9b3-fd82856656a9'	System	14 Sep 2020 18:28:20
User entered '14 Sep 2020 13:28'	System	14 Sep 2020 18:28:20

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:21:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	08 Sep 2020 17:36:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 17:36:00

US3292127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-08T12:59:10', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '669dd385-37f3-4e64-8dc8-a8c57722a57f'	System	08 Sep 2020 17:59:43
User entered 'None (1)'	System	08 Sep 2020 17:59:43

US3292127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-08T12:59:17', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '669dd385-37f3-4e64-8dc8-a8c57722a57f'	System	08 Sep 2020 17:59:43
User entered 'No (N)'	System	08 Sep 2020 17:59:43

US3292127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-08T12:59:28', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '669dd385-37f3-4e64-8dc8-a8c57722a57f'	System	08 Sep 2020 17:59:43
User entered 'No (N)'	System	08 Sep 2020 17:59:43

US3292127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-08T12:59:33', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '669dd385-37f3-4e64-8dc8-a8c57722a57f'	System	08 Sep 2020 17:59:43
User entered 'None (1)'	System	08 Sep 2020 17:59:43

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-08T12:59:38', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '669dd385-37f3-4e64-8dc8-a8c57722a57f'	System	08 Sep 2020 17:59:43
User entered '08 Sep 2020 12:59'	System	08 Sep 2020 17:59:43

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '08 Sep 2020 12:41'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '08 Sep 2020 15:11'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	08 Sep 2020 17:36:00
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 17:36:00

US3292127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:21:43

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:21:43
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)	04 Mar 2021 23:52:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:21:43
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)	04 Mar 2021 23:52:54

US3292127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:21:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '08 Sep 2020 16:06'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	08 Sep 2020 17:36:00
User entered 'Day 2'	System	08 Sep 2020 17:36:00

US3292127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:21:43

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-09T12:48:55', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'b57da5c9-1a84-4ef0-aec9-780c952c36ae'	System	09 Sep 2020 17:49:20
User entered 'None (1)'	System	09 Sep 2020 17:49:20

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-09T12:49:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'b57da5c9-1a84-4ef0-aec9-780c952c36ae'	System	09 Sep 2020 17:49:20
User entered 'No (N)'	System	09 Sep 2020 17:49:20

US3292127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-09T12:49:06', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'b57da5c9-1a84-4ef0-aec9-780c952c36ae'	System	09 Sep 2020 17:49:20
User entered 'No (N)'	System	09 Sep 2020 17:49:20

US3292127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:21:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-09T12:49:12', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'b57da5c9-1a84-4ef0-aec9-780c952c36ae'	System	09 Sep 2020 17:49:20
User entered 'None (1)'	System	09 Sep 2020 17:49:20

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:21:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-09T12:49:18', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'b57da5c9-1a84-4ef0-aec9-780c952c36ae'	System	09 Sep 2020 17:49:20
User entered '09 Sep 2020 12:49'	System	09 Sep 2020 17:49:20

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	08 Sep 2020 17:36:00
User entered 'Day 3'	System	08 Sep 2020 17:36:00

US3292127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-10T12:23:48', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'd5d61137-17d1-4cff-86a3-e5b3829cd60a'	System	10 Sep 2020 17:24:20
User entered 'None (1)'	System	10 Sep 2020 17:24:20

US3292127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-10T12:23:53', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'd5d61137-17d1-4cff-86a3-e5b3829cd60a'	System	10 Sep 2020 17:24:20
User entered 'No (N)'	System	10 Sep 2020 17:24:20

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-10T12:23:58', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'd5d61137-17d1-4cff-86a3-e5b3829cd60a'	System	10 Sep 2020 17:24:20
User entered 'No (N)'	System	10 Sep 2020 17:24:20

US3292127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-10T12:24:02', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'd5d61137-17d1-4cff-86a3-e5b3829cd60a'	System	10 Sep 2020 17:24:20
User entered 'None (1)'	System	10 Sep 2020 17:24:20

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:21:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-10T12:24:17', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'd5d61137-17d1-4cff-86a3-e5b3829cd60a'	System	10 Sep 2020 17:24:20
User entered '10 Sep 2020 12:24'	System	10 Sep 2020 17:24:20

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 17:36:00

US3292127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:21:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	08 Sep 2020 17:36:00
User entered 'Day 4'	System	08 Sep 2020 17:36:00

US3292127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-11T18:30:13', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'eaaad349-27bd-4717-ac1b-39ecdeb035f7'	System	11 Sep 2020 23:30:52
User entered 'None (1)'	System	11 Sep 2020 23:30:52

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US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-11T18:30:18', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'eaaad349-27bd-4717-ac1b-39ecdeb035f7'	System	11 Sep 2020 23:30:52
User entered 'No (N)'	System	11 Sep 2020 23:30:52

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-11T18:30:22', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'eaaad349-27bd-4717-ac1b-39ecdeb035f7'	System	11 Sep 2020 23:30:52
User entered 'No (N)'	System	11 Sep 2020 23:30:52

US3292127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:21:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-11T18:30:27', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'eaaad349-27bd-4717-ac1b-39ecdeb035f7'	System	11 Sep 2020 23:30:52
User entered 'None (1)'	System	11 Sep 2020 23:30:52

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:21:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-11T18:30:49', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'eaaad349-27bd-4717-ac1b-39ecdeb035f7'	System	11 Sep 2020 23:30:52
User entered '11 Sep 2020 18:30'	System	11 Sep 2020 23:30:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 17:36:00

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	08 Sep 2020 17:36:00
User entered 'Day 5'	System	08 Sep 2020 17:36:00

US3292127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-12T12:31:49', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '26277a22-cf23-4efe-b256-4d1c35f2ccba'	System	12 Sep 2020 17:32:21
User entered 'None (1)'	System	12 Sep 2020 17:32:21

US3292127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-12T12:31:53', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '26277a22-cf23-4efe-b256-4d1c35f2ccba'	System	12 Sep 2020 17:32:21
User entered 'No (N)'	System	12 Sep 2020 17:32:21

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:21:43
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-12T12:32:13', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '26277a22-cf23-4efe-b256-4d1c35f2ccba'	System	12 Sep 2020 17:32:21
User entered 'No (N)'	System	12 Sep 2020 17:32:21

US3292127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-12T12:32:02', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '26277a22-cf23-4efe-b256-4d1c35f2ccba'	System	12 Sep 2020 17:32:21
User entered 'None (1)'	System	12 Sep 2020 17:32:21

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:21:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-12T12:32:17', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '26277a22-cf23-4efe-b256-4d1c35f2ccba'	System	12 Sep 2020 17:32:21
User entered '12 Sep 2020 12:32'	System	12 Sep 2020 17:32:21

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 17:36:00

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	08 Sep 2020 17:36:00
User entered 'Day 6'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-13T12:28:09', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5fd28d60-fa98-41c0-a5dd-4de7b56491db'	System	13 Sep 2020 17:28:34
User entered 'None (1)'	System	13 Sep 2020 17:28:34

US3292127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-13T12:28:15', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5fd28d60-fa98-41c0-a5dd-4de7b56491db'	System	13 Sep 2020 17:28:34
User entered 'No (N)'	System	13 Sep 2020 17:28:34

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:21:43
Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-13T12:28:19', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5fd28d60-fa98-41c0-a5dd-4de7b56491db'	System	13 Sep 2020 17:28:34
User entered 'No (N)'	System	13 Sep 2020 17:28:34

US3292127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-13T12:28:25', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5fd28d60-fa98-41c0-a5dd-4de7b56491db'	System	13 Sep 2020 17:28:34
User entered 'None (1)'	System	13 Sep 2020 17:28:34

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:21:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-13T12:28:31', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5fd28d60-fa98-41c0-a5dd-4de7b56491db'	System	13 Sep 2020 17:28:34
User entered '13 Sep 2020 12:28'	System	13 Sep 2020 17:28:34

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 17:36:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 17:36:00

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US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	08 Sep 2020 17:36:00
User entered 'Day 7'	System	08 Sep 2020 17:36:00

US3292127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-14T13:28:24', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5fad93dd-ad82-4a7b-80ec-74718604bdc4'	System	14 Sep 2020 18:28:53
User entered 'None (1)'	System	14 Sep 2020 18:28:53

US3292127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-14T13:28:27', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5fad93dd-ad82-4a7b-80ec-74718604bdc4'	System	14 Sep 2020 18:28:53
User entered 'No (N)'	System	14 Sep 2020 18:28:53

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-14T13:28:34', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5fad93dd-ad82-4a7b-80ec-74718604bdc4'	System	14 Sep 2020 18:28:53
User entered 'No (N)'	System	14 Sep 2020 18:28:53

US3292127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-14T13:28:39', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5fad93dd-ad82-4a7b-80ec-74718604bdc4'	System	14 Sep 2020 18:28:53
User entered 'None (1)'	System	14 Sep 2020 18:28:53

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:21:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-14T13:28:49', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5fad93dd-ad82-4a7b-80ec-74718604bdc4'	System	14 Sep 2020 18:28:53
User entered '14 Sep 2020 13:28'	System	14 Sep 2020 18:28:53

US3292127
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 17:36:00

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	08 Sep 2020 17:36:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-08T12:59:44', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '63e2b8e2-085b-494f-8c08-70d934a6e2c6'	System	08 Sep 2020 18:00:16
User entered 'None (0)'	System	08 Sep 2020 18:00:16

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-08T12:59:47', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '63e2b8e2-085b-494f-8c08-70d934a6e2c6'	System	08 Sep 2020 18:00:16
User entered 'None (0)'	System	08 Sep 2020 18:00:16

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-08T12:59:51', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '63e2b8e2-085b-494f-8c08-70d934a6e2c6'	System	08 Sep 2020 18:00:16
User entered 'None (0)'	System	08 Sep 2020 18:00:16

US3292127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-08T12:59:54', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '63e2b8e2-085b-494f-8c08-70d934a6e2c6'	System	08 Sep 2020 18:00:16
User entered 'None (0)'	System	08 Sep 2020 18:00:16

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-08T12:59:57', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '63e2b8e2-085b-494f-8c08-70d934a6e2c6'	System	08 Sep 2020 18:00:16
User entered 'None (0)'	System	08 Sep 2020 18:00:16

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-08T13:00:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '63e2b8e2-085b-494f-8c08-70d934a6e2c6'	System	08 Sep 2020 18:00:16
User entered 'None (0)'	System	08 Sep 2020 18:00:16

US3292127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:21:43

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)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-08T13:00:05', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '63e2b8e2-085b-494f-8c08-70d934a6e2c6'	System	08 Sep 2020 18:00:16
User entered 'No (N)'	System	08 Sep 2020 18:00:16

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:21:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-08T13:00:12', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '63e2b8e2-085b-494f-8c08-70d934a6e2c6'	System	08 Sep 2020 18:00:16
User entered '08 Sep 2020 13:00'	System	08 Sep 2020 18:00:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '08 Sep 2020 12:41'	System	08 Sep 2020 17:36:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '08 Sep 2020 15:11'	System	08 Sep 2020 17:36:00

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US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	08 Sep 2020 17:36:00
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:21:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:21:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:21:43

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)	04 Mar 2021 23:52:54

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:21:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '08 Sep 2020 16:06'	System	08 Sep 2020 17:36:00

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PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	08 Sep 2020 17:36:00
User entered 'Day 2'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:21:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-09T12:49:24', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '092a0731-485e-4b83-83bb-5a4853498f0f'	System	09 Sep 2020 17:49:50
User entered 'None (0)'	System	09 Sep 2020 17:49:50

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:21:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-09T12:49:28', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '092a0731-485e-4b83-83bb-5a4853498f0f'	System	09 Sep 2020 17:49:50
User entered 'None (0)'	System	09 Sep 2020 17:49:50

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:21:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-09T12:49:31', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '092a0731-485e-4b83-83bb-5a4853498f0f'	System	09 Sep 2020 17:49:50
User entered 'None (0)'	System	09 Sep 2020 17:49:50

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:21:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-09T12:49:35', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '092a0731-485e-4b83-83bb-5a4853498f0f'	System	09 Sep 2020 17:49:50
User entered 'None (0)'	System	09 Sep 2020 17:49:50

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:21:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-09T12:49:38', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '092a0731-485e-4b83-83bb-5a4853498f0f'	System	09 Sep 2020 17:49:50
User entered 'None (0)'	System	09 Sep 2020 17:49:50

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:21:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-09T12:49:40', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '092a0731-485e-4b83-83bb-5a4853498f0f'	System	09 Sep 2020 17:49:50
User entered 'None (0)'	System	09 Sep 2020 17:49:50

US3292127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:21:43

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)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-09T12:49:45', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '092a0731-485e-4b83-83bb-5a4853498f0f'	System	09 Sep 2020 17:49:50
User entered 'No (N)'	System	09 Sep 2020 17:49:50

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:21:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-09T12:49:48', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '092a0731-485e-4b83-83bb-5a4853498f0f'	System	09 Sep 2020 17:49:50
User entered '09 Sep 2020 12:49'	System	09 Sep 2020 17:49:50

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:21:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	08 Sep 2020 17:36:00
User entered 'Day 3'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:21:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-10T12:24:27', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'fdf2f23e-e5ed-4336-9742-77fe8021f94d'	System	10 Sep 2020 17:25:19
User entered 'None (0)'	System	10 Sep 2020 17:25:19

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:21:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-10T12:24:33', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'fdf2f23e-e5ed-4336-9742-77fe8021f94d'	System	10 Sep 2020 17:25:19
User entered 'None (0)'	System	10 Sep 2020 17:25:19

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:21:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-10T12:24:37', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'fdf2f23e-e5ed-4336-9742-77fe8021f94d'	System	10 Sep 2020 17:25:19
User entered 'None (0)'	System	10 Sep 2020 17:25:19

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US3292127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-10T12:24:40', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'fdf2f23e-e5ed-4336-9742-77fe8021f94d'	System	10 Sep 2020 17:25:19
User entered 'None (0)'	System	10 Sep 2020 17:25:19

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:21:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-10T12:24:43', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'fdf2f23e-e5ed-4336-9742-77fe8021f94d'	System	10 Sep 2020 17:25:19
User entered 'None (0)'	System	10 Sep 2020 17:25:19

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:21:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-10T12:25:12', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'fdf2f23e-e5ed-4336-9742-77fe8021f94d'	System	10 Sep 2020 17:25:19
User entered 'None (0)'	System	10 Sep 2020 17:25:19

US3292127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:43

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)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-10T12:24:53', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'fdf2f23e-e5ed-4336-9742-77fe8021f94d'	System	10 Sep 2020 17:25:19
User entered 'No (N)'	System	10 Sep 2020 17:25:19

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:21:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-10T12:25:17', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'fdf2f23e-e5ed-4336-9742-77fe8021f94d'	System	10 Sep 2020 17:25:19
User entered '10 Sep 2020 12:25'	System	10 Sep 2020 17:25:19

US3292127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:21:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:21:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	08 Sep 2020 17:36:00
User entered 'Day 4'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:21:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-11T18:30:58', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '4f0c21ae-dba5-4dcf-a49d-3332e1cd06f8'	System	11 Sep 2020 23:31:45
User entered 'None (0)'	System	11 Sep 2020 23:31:45

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:21:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-11T18:31:04', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '4f0c21ae-dba5-4dcf-a49d-3332e1cd06f8'	System	11 Sep 2020 23:31:45
User entered 'None (0)'	System	11 Sep 2020 23:31:45

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:21:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-11T18:31:11', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '4f0c21ae-dba5-4dcf-a49d-3332e1cd06f8'	System	11 Sep 2020 23:31:45
User entered 'None (0)'	System	11 Sep 2020 23:31:45

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:21:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-11T18:31:17', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '4f0c21ae-dba5-4dcf-a49d-3332e1cd06f8'	System	11 Sep 2020 23:31:45
User entered 'None (0)'	System	11 Sep 2020 23:31:45

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:21:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-11T18:31:22', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '4f0c21ae-dba5-4dcf-a49d-3332e1cd06f8'	System	11 Sep 2020 23:31:45
User entered 'None (0)'	System	11 Sep 2020 23:31:45

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:21:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-11T18:31:25', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '4f0c21ae-dba5-4dcf-a49d-3332e1cd06f8'	System	11 Sep 2020 23:31:45
User entered 'None (0)'	System	11 Sep 2020 23:31:45

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:21:43
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)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-11T18:31:31', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '4f0c21ae-dba5-4dcf-a49d-3332e1cd06f8'	System	11 Sep 2020 23:31:45
User entered 'No (N)'	System	11 Sep 2020 23:31:45

US3292127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:43

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-11T18:31:44', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '4f0c21ae-dba5-4dcf-a49d-3332e1cd06f8'	System	11 Sep 2020 23:31:45
User entered '11 Sep 2020 18:31'	System	11 Sep 2020 23:31:45

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 17:36:00

US3292127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:21:43

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	08 Sep 2020 17:36:00
User entered 'Day 5'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:21:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-12T12:32:24', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'faf1d820-cdfa-4e39-b94b-d9a80e38a6d5'	System	12 Sep 2020 17:32:48
User entered 'None (0)'	System	12 Sep 2020 17:32:48

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:21:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-12T12:32:27', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'faf1d820-cdfa-4e39-b94b-d9a80e38a6d5'	System	12 Sep 2020 17:32:48
User entered 'None (0)'	System	12 Sep 2020 17:32:48

US3292127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-12T12:32:30', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'faf1d820-cdfa-4e39-b94b-d9a80e38a6d5'	System	12 Sep 2020 17:32:48
User entered 'None (0)'	System	12 Sep 2020 17:32:48

US3292127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:21:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-12T12:32:33', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'faf1d820-cdfa-4e39-b94b-d9a80e38a6d5'	System	12 Sep 2020 17:32:48
User entered 'None (0)'	System	12 Sep 2020 17:32:48

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:21:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-12T12:32:36', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'faf1d820-cdfa-4e39-b94b-d9a80e38a6d5'	System	12 Sep 2020 17:32:48
User entered 'None (0)'	System	12 Sep 2020 17:32:48

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:21:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-12T12:32:39', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'faf1d820-cdfa-4e39-b94b-d9a80e38a6d5'	System	12 Sep 2020 17:32:48
User entered 'None (0)'	System	12 Sep 2020 17:32:48

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:21:43

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)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-12T12:32:43', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'faf1d820-cdfa-4e39-b94b-d9a80e38a6d5'	System	12 Sep 2020 17:32:48
User entered 'No (N)'	System	12 Sep 2020 17:32:48

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:21:43

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-12T12:32:46', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'faf1d820-cdfa-4e39-b94b-d9a80e38a6d5'	System	12 Sep 2020 17:32:48
User entered '12 Sep 2020 12:32'	System	12 Sep 2020 17:32:48

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	08 Sep 2020 17:36:00
User entered 'Day 6'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:21:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-13T12:28:39', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'b4c28cc3-6610-4c06-b79d-9ee4b7fb131c'	System	13 Sep 2020 17:29:09
User entered 'None (0)'	System	13 Sep 2020 17:29:09

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:21:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-13T12:28:42', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'b4c28cc3-6610-4c06-b79d-9ee4b7fb131c'	System	13 Sep 2020 17:29:09
User entered 'None (0)'	System	13 Sep 2020 17:29:09

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:21:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-13T12:28:46', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'b4c28cc3-6610-4c06-b79d-9ee4b7fb131c'	System	13 Sep 2020 17:29:09
User entered 'None (0)'	System	13 Sep 2020 17:29:09

US3292127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-13T12:28:51', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'b4c28cc3-6610-4c06-b79d-9ee4b7fb131c'	System	13 Sep 2020 17:29:09
User entered 'None (0)'	System	13 Sep 2020 17:29:09

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:21:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-13T12:28:53', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'b4c28cc3-6610-4c06-b79d-9ee4b7fb131c'	System	13 Sep 2020 17:29:09
User entered 'None (0)'	System	13 Sep 2020 17:29:09

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:21:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-13T12:28:57', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'b4c28cc3-6610-4c06-b79d-9ee4b7fb131c'	System	13 Sep 2020 17:29:09
User entered 'None (0)'	System	13 Sep 2020 17:29:09

US3292127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:43

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)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-13T12:29:01', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'b4c28cc3-6610-4c06-b79d-9ee4b7fb131c'	System	13 Sep 2020 17:29:09
User entered 'No (N)'	System	13 Sep 2020 17:29:09

US3292127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:21:43

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-13T12:29:06', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'b4c28cc3-6610-4c06-b79d-9ee4b7fb131c'	System	13 Sep 2020 17:29:09
User entered '13 Sep 2020 12:29'	System	13 Sep 2020 17:29:09

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 17:36:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	08 Sep 2020 17:36:00
User entered 'Day 7'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:21:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-14T13:29:01', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5dd415eb-93ea-41fc-b7e7-6061bb9d2935'	System	14 Sep 2020 18:29:47
User entered 'None (0)'	System	14 Sep 2020 18:29:47

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:21:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-14T13:29:05', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5dd415eb-93ea-41fc-b7e7-6061bb9d2935'	System	14 Sep 2020 18:29:47
User entered 'None (0)'	System	14 Sep 2020 18:29:47

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:21:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-14T13:29:08', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5dd415eb-93ea-41fc-b7e7-6061bb9d2935'	System	14 Sep 2020 18:29:47
User entered 'None (0)'	System	14 Sep 2020 18:29:47

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:21:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-14T13:29:10', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5dd415eb-93ea-41fc-b7e7-6061bb9d2935'	System	14 Sep 2020 18:29:47
User entered 'None (0)'	System	14 Sep 2020 18:29:47

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:21:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-14T13:29:13', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5dd415eb-93ea-41fc-b7e7-6061bb9d2935'	System	14 Sep 2020 18:29:47
User entered 'None (0)'	System	14 Sep 2020 18:29:47

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:21:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-14T13:29:17', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5dd415eb-93ea-41fc-b7e7-6061bb9d2935'	System	14 Sep 2020 18:29:47
User entered 'None (0)'	System	14 Sep 2020 18:29:47

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:21:43

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)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-14T13:29:26', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5dd415eb-93ea-41fc-b7e7-6061bb9d2935'	System	14 Sep 2020 18:29:47
User entered 'No (N)'	System	14 Sep 2020 18:29:47

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:21:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-09-14T13:29:44', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '5dd415eb-93ea-41fc-b7e7-6061bb9d2935'	System	14 Sep 2020 18:29:47
User entered '14 Sep 2020 13:29'	System	14 Sep 2020 18:29:47

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:21:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 17:36:00

US3292127
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:21:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 17:36:00

US3292127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:43

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:57:44
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	16 Sep 2020 18:56:15

US3292127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:43

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:57:44
User entered '16 Sep 2020'	Kristy Trevino (b) (4) (b) (4)	16 Sep 2020 18:56:15

US3292127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:21:43

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:57:44
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4) (b) (4)	16 Sep 2020 18:56:15

US3292127
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:57:44
User entered empty.	Kristy Trevino (b) (4) (b) (4)	16 Sep 2020 18:56:15

US3292127

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 17:58:10
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	16 Sep 2020 18:56:22

US3292127
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered '1'	System	16 Sep 2020 18:56:22

US3292127
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 17:59:07
User entered 'Yes (Y)'		23 Sep 2020 17:48:51

US3292127
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 17:59:07
User entered '23 Sep 2020'		23 Sep 2020 17:48:51

Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 17:59:07
User entered 'Contact Made (CONTACT MADE)'		23 Sep 2020 17:48:51

US3292127
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 17:59:07
User entered empty.		23 Sep 2020 17:48:51

US3292127
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 17:59:41
User entered 'Yes (Y)'		30 Sep 2020 17:08:22

US3292127
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered '1'	System	30 Sep 2020 17:08:22

US3292127
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:00:23
User entered 'Yes (Y)'		30 Sep 2020 17:13:44

US3292127
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:00:23
User entered '30 Sep 2020'		30 Sep 2020 17:13:44

US3292127
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 18:00:23
User entered 'Contact Made (CONTACT MADE)'		30 Sep 2020 17:13:44

US3292127
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:00:23
User entered empty.		30 Sep 2020 17:13:44

US3292127

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:00:45
User entered 'Yes (Y)'		30 Sep 2020 17:13:51

US3292127
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered '1'	System	30 Sep 2020 17:13:51

US3292127
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:21:43
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:58:29
User entered 'Yes (Y)'		06 Oct 2020 17:36:34

US3292127
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:21:43
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:58:29
User entered '6 Oct 2020'		06 Oct 2020 17:36:34

US3292127
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:58:29
User entered 'Clinic (Clinic)'		06 Oct 2020 17:36:34

US3292127
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:21:43
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'VISIT3'	System	06 Oct 2020 17:36:34

US3292127
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:58:58
User entered 'Yes (Y)'		06 Oct 2020 17:36:22

US3292127
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:58:58
User entered '6 Oct 2020'		06 Oct 2020 17:36:22

US3292127
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:58:58
User entered '09:58'		06 Oct 2020 17:36:22

US3292127
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered '6 Oct 2020 09:58'	System	06 Oct 2020 17:36:22

US3292127
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:58:58
User entered '37.8' C		06 Oct 2020 17:36:22

US3292127
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:58:58
User entered 'Oral (Oral)'		06 Oct 2020 17:36:22

US3292127
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:58:58
User entered empty.		06 Oct 2020 17:36:22

US3292127
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:58:58
User entered '83'		06 Oct 2020 17:36:22

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'bpm'	System	06 Oct 2020 17:36:22

US3292127
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:58:58
User entered '20'		06 Oct 2020 17:36:22

US3292127
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'breaths/min'	System	06 Oct 2020 17:36:22

US3292127
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:58:58
User entered '186'		06 Oct 2020 17:36:22

US3292127
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'mmHg'	System	06 Oct 2020 17:36:22

US3292127
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:58:58
User entered '96'		06 Oct 2020 17:36:22

US3292127
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered 'mmHg'	System	06 Oct 2020 17:36:22

US3292127
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38

US3292127
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38

US3292127

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:21:43

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:59:23
User entered 'No (N)'		06 Oct 2020 17:36:45

US3292127

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:21:43

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:59:23
User entered empty.		06 Oct 2020 17:36:45

US3292127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:43

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:59:39
User entered 'Yes (Y)'		06 Oct 2020 17:37:10

US3292127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:43

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:59:39
User entered '6 Oct 2020'		06 Oct 2020 17:37:10

US3292127
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:21:43
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:59:39
User entered '10:10'		06 Oct 2020 17:37:10

US3292127
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:21:43
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered '6 Oct 2020 10:10'	System	06 Oct 2020 17:37:10

US3292127
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:59:42
User entered 'Yes (Y)'		06 Oct 2020 17:37:13

US3292127
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered '1'	System	06 Oct 2020 17:37:13

US3292127
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 64'	System	11 Aug 2020 19:15:27

US3292127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-10-12T14:22:22', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '187e3533-0d4a-4bd9-8716-382007bb68c9'	System	12 Oct 2020 19:22:49
User entered 'No (N)'	System	12 Oct 2020 19:22:49

US3292127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you been exposed to someone with 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)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-10-12T14:22:33', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '187e3533-0d4a-4bd9-8716-382007bb68c9'	System	12 Oct 2020 19:22:49
User entered 'No (N)'	System	12 Oct 2020 19:22:49

US3292127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-10-12T14:22:46', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '187e3533-0d4a-4bd9-8716-382007bb68c9'	System	12 Oct 2020 19:22:49
User entered '12 Oct 2020 14:22:46'	System	12 Oct 2020 19:22:49

US3292127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 19:15:27

US3292127
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 19:15:27

US3292127
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 71'	System	11 Aug 2020 19:15:27

US3292127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-10-19T11:30:07', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '147d0804-1323-4b39-aceb-810324d55327'	System	19 Oct 2020 16:30:56
User entered 'No (N)'	System	19 Oct 2020 16:30:56

US3292127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you been exposed to someone with 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)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-10-19T11:30:30', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '147d0804-1323-4b39-aceb-810324d55327'	System	19 Oct 2020 16:30:56
User entered 'No (N)'	System	19 Oct 2020 16:30:56

US3292127
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-10-19T11:30:51', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '147d0804-1323-4b39-aceb-810324d55327'	System	19 Oct 2020 16:30:56
User entered '19 Oct 2020 11:30:51'	System	19 Oct 2020 16:30:56

US3292127
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 19:15:27

US3292127
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 19:15:27

US3292127
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 78'	System	11 Aug 2020 19:15:27

US3292127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-10-26T14:45:54', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '0de6cda7-1f12-4169-9fcb-0ff35f375675'	System	26 Oct 2020 19:46:35
User entered 'No (N)'	System	26 Oct 2020 19:46:35

US3292127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you been exposed to someone with 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)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-10-26T14:46:06', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '0de6cda7-1f12-4169-9fcb-0ff35f375675'	System	26 Oct 2020 19:46:35
User entered 'No (N)'	System	26 Oct 2020 19:46:35

US3292127
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-10-26T14:46:29', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '0de6cda7-1f12-4169-9fcb-0ff35f375675'	System	26 Oct 2020 19:46:35
User entered '26 Oct 2020 14:46:29'	System	26 Oct 2020 19:46:35

US3292127
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 19:15:27

US3292127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 19:15:27

US3292127
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 92'	System	11 Aug 2020 19:15:27

US3292127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-11-09T10:40:20', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '7cbe1dbd-6356-4023-a5a3-095bd98fa5f6'	System	09 Nov 2020 16:40:50
User entered 'No (N)'	System	09 Nov 2020 16:40:50

US3292127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you been exposed to someone with 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)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-11-09T10:40:31', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '7cbe1dbd-6356-4023-a5a3-095bd98fa5f6'	System	09 Nov 2020 16:40:50
User entered 'No (N)'	System	09 Nov 2020 16:40:50

US3292127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-11-09T10:40:46', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '7cbe1dbd-6356-4023-a5a3-095bd98fa5f6'	System	09 Nov 2020 16:40:50
User entered '09 Nov 2020 10:40:46'	System	09 Nov 2020 16:40:50

US3292127
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 19:15:27

US3292127
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 19:15:27

US3292127
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered 'Day 99'	System	11 Aug 2020 19:15:27

US3292127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-11-16T09:42:45', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '33c12d4e-cec3-4eaf-b436-da532a1e64f0'	System	16 Nov 2020 15:43:22
User entered 'No (N)'	System	16 Nov 2020 15:43:22

US3292127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you been exposed to someone with 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)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-11-16T09:43:04', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '33c12d4e-cec3-4eaf-b436-da532a1e64f0'	System	16 Nov 2020 15:43:22
User entered 'No (N)'	System	16 Nov 2020 15:43:22

US3292127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-11-16T09:43:19', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '33c12d4e-cec3-4eaf-b436-da532a1e64f0'	System	16 Nov 2020 15:43:22
User entered '16 Nov 2020 09:43:19'	System	16 Nov 2020 15:43:22

US3292127
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 19:15:27

US3292127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:52:54
Data entry locked.	System	11 Aug 2020 19:15:27
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 19:15:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:59:20

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US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-11-20T09:28:56', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'f48d23b6-4084-402e-a1d0-8c8ab198d808'	System	20 Nov 2020 15:29:22
User entered 'No (N)'	System	20 Nov 2020 15:29:22

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you been exposed to someone with 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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-11-20T09:29:10', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'f48d23b6-4084-402e-a1d0-8c8ab198d808'	System	20 Nov 2020 15:29:22
User entered 'No (N)'	System	20 Nov 2020 15:29:22

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-11-20T09:29:20', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'f48d23b6-4084-402e-a1d0-8c8ab198d808'	System	20 Nov 2020 15:29:22
User entered '20 Nov 2020 09:29:20'	System	20 Nov 2020 15:29:22

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 03:59:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-12-05T09:11:58', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '06a1cee9-950a-4e4e-8c38-2df90b68d0bd'	System	05 Dec 2020 15:13:13
User entered 'Yes (Y)'	System	05 Dec 2020 15:13:13

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you been exposed to someone with 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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-12-05T09:12:05', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '06a1cee9-950a-4e4e-8c38-2df90b68d0bd'	System	05 Dec 2020 15:13:13
User entered 'No (N)'	System	05 Dec 2020 15:13:13

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-12-05T09:12:15', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '06a1cee9-950a-4e4e-8c38-2df90b68d0bd'	System	05 Dec 2020 15:13:13
User entered 'No (N)'	System	05 Dec 2020 15:13:13

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-12-05T09:12:42', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '06a1cee9-950a-4e4e-8c38-2df90b68d0bd'	System	05 Dec 2020 15:13:13
User entered 'Yes (Y)'	System	05 Dec 2020 15:13:13

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-12-05T09:12:55', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '06a1cee9-950a-4e4e-8c38-2df90b68d0bd'	System	05 Dec 2020 15:13:13
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Dec 2020 15:13:13

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-12-05T09:13:02', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '06a1cee9-950a-4e4e-8c38-2df90b68d0bd'	System	05 Dec 2020 15:13:13
User entered '05 Dec 2020 09:13:02'	System	05 Dec 2020 15:13:13

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-12-12T08:33:01', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'a0659f81-35a4-4665-b440-164b7a4b7b7f'	System	12 Dec 2020 14:33:22
User entered 'No (N)'	System	12 Dec 2020 14:33:22

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you been exposed to someone with 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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-12-12T08:33:07', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'a0659f81-35a4-4665-b440-164b7a4b7b7f'	System	12 Dec 2020 14:33:22
User entered 'No (N)'	System	12 Dec 2020 14:33:22

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2020-12-12T08:33:19', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'a0659f81-35a4-4665-b440-164b7a4b7b7f'	System	12 Dec 2020 14:33:22
User entered '12 Dec 2020 08:33:19'	System	12 Dec 2020 14:33:22

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-01-01T21:06:26', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '4c0efb60-18b3-441f-86d2-19fba4048e3c'	System	02 Jan 2021 03:06:55
User entered 'No (N)'	System	02 Jan 2021 03:06:55

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you been exposed to someone with 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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-01-01T21:06:31', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '4c0efb60-18b3-441f-86d2-19fba4048e3c'	System	02 Jan 2021 03:06:55
User entered 'No (N)'	System	02 Jan 2021 03:06:55

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-01-01T21:06:50', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '4c0efb60-18b3-441f-86d2-19fba4048e3c'	System	02 Jan 2021 03:06:55
User entered '01 Jan 2021 21:06:50'	System	02 Jan 2021 03:06:55

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-01-08T11:45:57', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '7b460693-0cd5-4a0b-8c67-413d5499f427'	System	08 Jan 2021 17:46:10
User entered 'No (N)'	System	08 Jan 2021 17:46:10

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you been exposed to someone with 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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-01-08T11:46:01', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '7b460693-0cd5-4a0b-8c67-413d5499f427'	System	08 Jan 2021 17:46:10
User entered 'No (N)'	System	08 Jan 2021 17:46:10

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-01-08T11:46:08', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '7b460693-0cd5-4a0b-8c67-413d5499f427'	System	08 Jan 2021 17:46:10
User entered '08 Jan 2021 11:46:08'	System	08 Jan 2021 17:46:10

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 03:59:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-01-14T14:52:33', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '0137465a-5f27-497d-af50-aa916780b0dc'	System	14 Jan 2021 20:52:53
User entered 'No (N)'	System	14 Jan 2021 20:52:53

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you been exposed to someone with 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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-01-14T14:52:39', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '0137465a-5f27-497d-af50-aa916780b0dc'	System	14 Jan 2021 20:52:53
User entered 'No (N)'	System	14 Jan 2021 20:52:53

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-01-14T14:52:46', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '0137465a-5f27-497d-af50-aa916780b0dc'	System	14 Jan 2021 20:52:53
User entered '14 Jan 2021 14:52:46'	System	14 Jan 2021 20:52:53

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-01-25T12:48:30', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '280167b6-7112-478e-946b-03f82f84fcc6'	System	25 Jan 2021 18:48:50
User entered 'No (N)'	System	25 Jan 2021 18:48:50

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you been exposed to someone with 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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-01-25T12:48:36', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '280167b6-7112-478e-946b-03f82f84fcc6'	System	25 Jan 2021 18:48:50
User entered 'No (N)'	System	25 Jan 2021 18:48:50

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-01-25T12:48:47', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '280167b6-7112-478e-946b-03f82f84fcc6'	System	25 Jan 2021 18:48:50
User entered '25 Jan 2021 12:48:47'	System	25 Jan 2021 18:48:50

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-01-29T12:16:40', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'dca6c38f-df01-488b-97c3-bfc2fd73ead0'	System	29 Jan 2021 18:18:28
User entered 'Yes (Y)'	System	29 Jan 2021 18:18:28

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you been exposed to someone with 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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-01-29T12:17:03', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'dca6c38f-df01-488b-97c3-bfc2fd73ead0'	System	29 Jan 2021 18:18:28
User entered 'Yes (Y)'	System	29 Jan 2021 18:18:28

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-01-29T12:17:23', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'dca6c38f-df01-488b-97c3-bfc2fd73ead0'	System	29 Jan 2021 18:18:28
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Jan 2021 18:18:28

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-01-29T12:17:43', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'dca6c38f-df01-488b-97c3-bfc2fd73ead0'	System	29 Jan 2021 18:18:28
User entered 'No (N)'	System	29 Jan 2021 18:18:28

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-01-29T12:17:55', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'dca6c38f-df01-488b-97c3-bfc2fd73ead0'	System	29 Jan 2021 18:18:28
User entered 'No (N)'	System	29 Jan 2021 18:18:28

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-01-29T12:18:12', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'dca6c38f-df01-488b-97c3-bfc2fd73ead0'	System	29 Jan 2021 18:18:28
User entered '29 Jan 2021 12:18:12'	System	29 Jan 2021 18:18:28

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-02-08T07:11:30', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '94a42f51-6cd0-40bf-a53a-71594867d9dd'	System	08 Feb 2021 13:11:48
User entered 'No (N)'	System	08 Feb 2021 13:11:48

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you been exposed to someone with 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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-02-08T07:11:37', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '94a42f51-6cd0-40bf-a53a-71594867d9dd'	System	08 Feb 2021 13:11:48
User entered 'No (N)'	System	08 Feb 2021 13:11:48

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-02-08T07:11:43', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '94a42f51-6cd0-40bf-a53a-71594867d9dd'	System	08 Feb 2021 13:11:48
User entered '08 Feb 2021 07:11:43'	System	08 Feb 2021 13:11:48

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 03:59:20

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-02-12T13:40:09', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '4f585edc-e41c-42c2-b6c0-6d89b70ffe56'	System	12 Feb 2021 19:40:32
User entered 'No (N)'	System	12 Feb 2021 19:40:32

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you been exposed to someone with 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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-02-12T13:40:21', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '4f585edc-e41c-42c2-b6c0-6d89b70ffe56'	System	12 Feb 2021 19:40:32
User entered 'No (N)'	System	12 Feb 2021 19:40:32

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-02-12T13:40:28', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '4f585edc-e41c-42c2-b6c0-6d89b70ffe56'	System	12 Feb 2021 19:40:32
User entered '12 Feb 2021 13:40:28'	System	12 Feb 2021 19:40:32

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-02-25T11:28:41', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '3d4c71bf-6a6e-4f6c-968c-2e2b197e3895'	System	25 Feb 2021 17:29:48
User entered 'No (N)'	System	25 Feb 2021 17:29:48

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you been exposed to someone with 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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-02-25T11:28:47', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '3d4c71bf-6a6e-4f6c-968c-2e2b197e3895'	System	25 Feb 2021 17:29:48
User entered 'No (N)'	System	25 Feb 2021 17:29:48

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-02-25T11:28:54', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '3d4c71bf-6a6e-4f6c-968c-2e2b197e3895'	System	25 Feb 2021 17:29:48
User entered '25 Feb 2021 11:28:54'	System	25 Feb 2021 17:29:48

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 03:59:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-03-05T13:39:56-06:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '2640a202-95d8-49da-ae32-f934ea89ef5f'	System	05 Mar 2021 20:58:52
User entered 'No (N)'	System	05 Mar 2021 20:58:52

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you been exposed to someone with 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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-03-05T13:40:01-06:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '2640a202-95d8-49da-ae32-f934ea89ef5f'	System	05 Mar 2021 20:58:52
User entered 'No (N)'	System	05 Mar 2021 20:58:52

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-03-05T13:40:05-06:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '2640a202-95d8-49da-ae32-f934ea89ef5f'	System	05 Mar 2021 20:58:52
User entered '05 Mar 2021 13:40:05'	System	05 Mar 2021 20:58:52

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-03-12T09:24:23-06:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '4ba10bf2-b4c5-48e3-8ae3-3097d755479a'	System	12 Mar 2021 15:24:38
User entered 'No (N)'	System	12 Mar 2021 15:24:38

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you been exposed to someone with 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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-03-12T09:24:32-06:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '4ba10bf2-b4c5-48e3-8ae3-3097d755479a'	System	12 Mar 2021 15:24:38
User entered 'No (N)'	System	12 Mar 2021 15:24:38

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-03-12T09:24:35-06:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '4ba10bf2-b4c5-48e3-8ae3-3097d755479a'	System	12 Mar 2021 15:24:38
User entered '12 Mar 2021 09:24:35'	System	12 Mar 2021 15:24:38

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-03-20T11:08:39-05:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '96c1d33f-c9d9-4ba0-bef2-27f36c5f8db5'	System	20 Mar 2021 16:14:08
User entered 'No (N)'	System	20 Mar 2021 16:14:08

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you been exposed to someone with 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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-03-20T11:08:43-05:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '96c1d33f-c9d9-4ba0-bef2-27f36c5f8db5'	System	20 Mar 2021 16:14:08
User entered 'No (N)'	System	20 Mar 2021 16:14:08

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-03-20T11:08:47-05:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '96c1d33f-c9d9-4ba0-bef2-27f36c5f8db5'	System	20 Mar 2021 16:14:08
User entered '20 Mar 2021 11:08:47'	System	20 Mar 2021 16:14:08

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 03:59:20

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-03-27T16:26:31-05:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'e982a8d2-b830-4490-b389-608dca14661e'	System	27 Mar 2021 21:26:48
User entered 'No (N)'	System	27 Mar 2021 21:26:48

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you been exposed to someone with 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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-03-27T16:26:40-05:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'e982a8d2-b830-4490-b389-608dca14661e'	System	27 Mar 2021 21:26:48
User entered 'No (N)'	System	27 Mar 2021 21:26:48

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-03-27T16:26:44-05:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'e982a8d2-b830-4490-b389-608dca14661e'	System	27 Mar 2021 21:26:48
User entered '27 Mar 2021 16:26:44'	System	27 Mar 2021 21:26:48

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-04-01T13:49:03-05:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '359c149f-d091-4639-a3a1-e41dfc1626a7'	System	01 Apr 2021 18:49:26
User entered 'No (N)'	System	01 Apr 2021 18:49:26

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you been exposed to someone with 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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-04-01T13:49:08-05:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '359c149f-d091-4639-a3a1-e41dfc1626a7'	System	01 Apr 2021 18:49:26
User entered 'No (N)'	System	01 Apr 2021 18:49:26

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-04-01T13:49:16-05:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '359c149f-d091-4639-a3a1-e41dfc1626a7'	System	01 Apr 2021 18:49:26
User entered '01 Apr 2021 13:49:16'	System	01 Apr 2021 18:49:26

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-04-15T11:42:53-05:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'a45876c8-4df8-40c5-930f-86ad63f9a4a1'	System	15 Apr 2021 16:43:16
User entered 'No (N)'	System	15 Apr 2021 16:43:16

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you been exposed to someone with 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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-04-15T11:43:01-05:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'a45876c8-4df8-40c5-930f-86ad63f9a4a1'	System	15 Apr 2021 16:43:16
User entered 'No (N)'	System	15 Apr 2021 16:43:16

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-04-15T11:43:10-05:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'a45876c8-4df8-40c5-930f-86ad63f9a4a1'	System	15 Apr 2021 16:43:16
User entered '15 Apr 2021 11:43:10'	System	15 Apr 2021 16:43:16

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-04-22T15:15:14-05:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'a377f50d-3545-4837-837a-5354cb838f50'	System	22 Apr 2021 20:15:25
User entered 'No (N)'	System	22 Apr 2021 20:15:25

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you been exposed to someone with 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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-04-22T15:15:19-05:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'a377f50d-3545-4837-837a-5354cb838f50'	System	22 Apr 2021 20:15:25
User entered 'No (N)'	System	22 Apr 2021 20:15:25

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-04-22T15:15:23-05:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: 'a377f50d-3545-4837-837a-5354cb838f50'	System	22 Apr 2021 20:15:25
User entered '22 Apr 2021 15:15:23'	System	22 Apr 2021 20:15:25

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-04-29T14:18:43-05:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '4bb0fe9c-0137-4219-843a-ea329dafe9c9'	System	29 Apr 2021 19:19:01
User entered 'No (N)'	System	29 Apr 2021 19:19:01

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Have you been exposed to someone with 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 (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-04-29T14:18:50-05:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '4bb0fe9c-0137-4219-843a-ea329dafe9c9'	System	29 Apr 2021 19:19:01
User entered 'No (N)'	System	29 Apr 2021 19:19:01

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-04-29T14:18:54-05:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '4bb0fe9c-0137-4219-843a-ea329dafe9c9'	System	29 Apr 2021 19:19:01
User entered '29 Apr 2021 14:18:54'	System	29 Apr 2021 19:19:01

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 03:59:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 03:59:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:59:20

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US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:59:20

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 03:59:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:59:20

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US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 03:59:20

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:59:20

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 03:59:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 03:59:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 03:59:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:59:20

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US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 03:59:20

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 03:59:20

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 03:59:20

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 03:59:20

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:59:20

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:59:20

US3292127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:21:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 03:59:20

US3292127
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:21:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:59:20
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 03:59:20

US3292127

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:21:43

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-03-05T13:40:19-06:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '8b7a2a8e-0760-48de-add0-2d12d8aa9608'	System	05 Mar 2021 20:59:17
User entered 'No (N)'	System	05 Mar 2021 20:59:17

US3292127

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:21:43

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C2AB269-BD19-4BF0-BBF9-021BF01F08D3)', Time: '2021-03-05T13:40:27-06:00', User OID: 'PatientReportedOutcome (US3292127)', ODM File OID: '8b7a2a8e-0760-48de-add0-2d12d8aa9608'	System	05 Mar 2021 20:59:17
User entered '05 Mar 2021 13:40:27'	System	05 Mar 2021 20:59:17

US3292127
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:01:38
User entered 'Yes (Y)'		03 Nov 2020 17:31:11

US3292127
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:01:38
User entered '3 Nov 2020'		03 Nov 2020 17:31:11

US3292127
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:01:38
User entered 'Contact Made (CONTACT MADE)'		03 Nov 2020 17:31:11

US3292127
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:01:38
User entered empty.		03 Nov 2020 17:31:11

US3292127
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:01:57
User entered 'Yes (Y)'		03 Nov 2020 17:31:16

US3292127
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:52:38
User entered '1'	System	03 Nov 2020 17:31:16

US3292127
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:27:28
DataPoint Verified.		05 Mar 2021 15:01:01
User signature succeeded.	(b) (4)	22 Feb 2021 18:47:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 14:13:43

US3292127
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:27:28
DataPoint Verified.		05 Mar 2021 15:01:01
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
User entered '7 Dec 2020'	(b) (4), (b) (6)	09 Dec 2020 14:13:43

US3292127
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:27:28
DataPoint Verified.		05 Mar 2021 15:01:01
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Dec 2020 14:13:43

US3292127
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:27:28
DataPoint Verified.		05 Mar 2021 15:01:01
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
User entered empty.	(b) (4), (b) (6)	09 Dec 2020 14:13:43

US3292127
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:27:28
DataPoint Verified.		05 Mar 2021 15:01:36
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Dec 2020 14:13:49

US3292127
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:27:28
User entered '1'	System	09 Dec 2020 14:13:49

US3292127
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:27:28
DataPoint Verified.		05 Mar 2021 15:01:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 15:37:28

US3292127
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:27:28
DataPoint Verified.		05 Mar 2021 15:01:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
User entered '5 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 15:37:28

US3292127
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:27:28
DataPoint Verified.		05 Mar 2021 15:01:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Jan 2021 15:37:28

US3292127
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:27:28
DataPoint Verified.		05 Mar 2021 15:01:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
User entered empty.	(b) (4) (b) (4), (6)	06 Jan 2021 15:37:28

US3292127

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:27:28
DataPoint Verified.		05 Mar 2021 15:02:05
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 15:37:36

US3292127
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:27:28
User entered '1'	System	06 Jan 2021 15:37:36

US3292127
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:57
DataPoint Verified.		05 Mar 2021 15:02:21
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Feb 2021 16:51:46

US3292127
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:57
DataPoint Verified.		05 Mar 2021 15:02:21
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered '4 Feb 2021'	(b) (4), (b) (6)	27 Feb 2021 16:51:46

US3292127
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:57
DataPoint Verified.		05 Mar 2021 15:02:21
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	03 Mar 2021 14:12:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Feb 2021 16:51:46

US3292127
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:57
DataPoint Verified.		05 Mar 2021 15:02:21
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered empty.	(b) (4), (b) (6)	27 Feb 2021 16:51:46

US3292127
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:57
DataPoint Verified.		05 Mar 2021 15:02:41
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Feb 2021 16:51:50

US3292127
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:57
User entered '1'	System	27 Feb 2021 16:51:50

US3292127
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:21:43

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:35
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:35:17
User entered 'Yes (Y)'		19 Mar 2021 15:19:12

US3292127
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:21:43
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:35:17
User entered '5 Mar 2021'		19 Mar 2021 15:19:12

US3292127
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:21:43

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 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:35:17
User entered 'Clinic (Clinic)'		19 Mar 2021 15:19:12

US3292127
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:21:43
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered 'VISIT4'	System	19 Mar 2021 15:19:12

US3292127
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:35:21
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:09:52

US3292127
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:35:21
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:09:52

US3292127
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:35:21
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:09:52

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered empty.	System	29 Mar 2021 19:09:52

US3292127
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:35:21
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:09:52

US3292127
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:35:21
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:09:52

US3292127
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:35:21
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:09:52

US3292127
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:35:21
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:09:52

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered empty.	System	29 Mar 2021 19:09:52

US3292127
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:35:21
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:09:52

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered empty.	System	29 Mar 2021 19:09:52

US3292127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:21:43

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:35:21
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:09:52

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered empty.	System	29 Mar 2021 19:09:52

US3292127
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:35:21
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:09:52

US3292127
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered empty.	System	29 Mar 2021 19:09:52

US3292127
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34

US3292127
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34

US3292127
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:21:43
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:35
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:35:28
User entered 'No (N)'		19 Mar 2021 15:19:36

US3292127
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:21:43
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:35
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:35:28
User entered empty.		19 Mar 2021 15:19:36

US3292127

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:43

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:35:37
User entered 'Yes (Y)'		19 Mar 2021 15:20:02

US3292127

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:43

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:35:37
User entered '05 Mar 2021'		19 Mar 2021 15:20:02

US3292127

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:35:37
User entered '12:04'		19 Mar 2021 15:20:02

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered '05 Mar 2021 12:04'	System	19 Mar 2021 15:20:02

US3292127
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:35
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:35:41
User entered 'Yes (Y)'		19 Mar 2021 15:20:08

US3292127
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:25:34
User entered '1'	System	19 Mar 2021 15:20:08

US3292127
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43

Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:03:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 21:00:36

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:06
User entered '6 Apr 2021'	(b) (4), (b) (6)	08 Apr 2021 21:00:36

US3292127
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43

Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Apr 2021 21:00:36

US3292127
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:03:06
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 21:00:36

US3292127
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:03:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 21:00:40

US3292127

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:43

Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 21:00:40

US3292127
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:21:43

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:50:31
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:33:26

US3292127

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

Form: Visit Date

Generated On: 09 Jun 2021 16:21:43

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:50:31
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '28 Jan 2021'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:33:26

US3292127

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

Form: Visit Date

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:50:31
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered 'Clinic (Clinic)'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:33:26

US3292127
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:21:43
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered 'UNBLND_DECIDE'	System	28 Jan 2021 23:33:26

US3292127

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

Form: Unblinding

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:51:52
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '28 Jan 2021'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:34:27

US3292127

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

Form: Unblinding

Generated On: 09 Jun 2021 16:21:43

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:47:42

US3292127

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

Form: Unblinding

Generated On: 09 Jun 2021 16:21:43

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:51:52
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:34:27

US3292127

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

Form: Unblinding

Generated On: 09 Jun 2021 16:21:43

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:47:42

US3292127
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:21:43

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:51:52
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '28 Jan 2021'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:34:27

US3292127

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

Form: Unblinding

Generated On: 09 Jun 2021 16:21:43

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:51:52
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered 'Placebo (Placebo)'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:34:27

US3292127
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:21:43
Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:51:52
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered 'Placebo (Placebo)'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:34:27

US3292127
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:21:43
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:51:52
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered 'Placebo (Placebo)'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:34:27

US3292127

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

Form: Unblinding

Generated On: 09 Jun 2021 16:21:43

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:51:52
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:34:27

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered '1'	System	28 Jan 2021 23:34:27

US3292127
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:21:43
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered '1'	System	28 Jan 2021 23:34:27

US3292127

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:21:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered missing code ND - Not Done.	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:21:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered missing code ND - Not Done.	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

US3292127
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:21:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered empty.	System	28 Jan 2021 23:37:00
DataPoint set to visible.	System	28 Jan 2021 23:34:27

US3292127
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:21:43
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered missing code ND - Not Done.	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:21:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered missing code ND - Not Done.	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered empty.	System	28 Jan 2021 23:37:00
DataPoint set to visible.	System	28 Jan 2021 23:34:27

US3292127

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User accepted default value 'Pre-Dose (PREDOSE)'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '28 Jan 2021'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '14:37'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered '28 Jan 2021 14:37'	System	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '37.1' C	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered 'Oral (Oral)'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered empty.	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '81'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

US3292127
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:21:43

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered 'bpm'	System	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
User entered '16'	Dawn Killian (b) (4)	28 Jan 2021 23:37:00

Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:21:43

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered 'breaths/min'	System	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '162'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered 'mmHg'	System	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '91'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:21:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered 'mmHg'	System	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:21:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered missing code ND - Not Done.	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:21:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered missing code ND - Not Done.	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

US3292127
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:21:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered empty.	System	28 Jan 2021 23:37:00
DataPoint set to visible.	System	28 Jan 2021 23:34:27

US3292127

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User accepted default value 'Post-Dose (POSTDOSE)'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '28 Jan 2021'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '15:53'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

US3292127
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:21:43

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered '28 Jan 2021 15:53'	System	28 Jan 2021 23:37:00

US3292127
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:21:43

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '36.5' C	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered 'Oral (Oral)'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered empty.	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '78'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

US3292127
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:21:43
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered 'bpm'	System	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '16'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

US3292127
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:21:43
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered 'breaths/min'	System	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '176'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered 'mmHg'	System	28 Jan 2021 23:37:00

US3292127

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '91'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:37:00

US3292127
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:21:43
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered 'mmHg'	System	28 Jan 2021 23:37:00

US3292127
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:21:43
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:55
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:34:35

US3292127

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:21:43

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:56:55
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '28 Jan 2021'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:34:35

US3292127

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

Form: Exposure

Generated On: 09 Jun 2021 16:21:43

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:58:50
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:34:46

US3292127

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

Form: Exposure

Generated On: 09 Jun 2021 16:21:43

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:58:50
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered empty.	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:34:46

US3292127

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

Form: Exposure

Generated On: 09 Jun 2021 16:21:43

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)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:58:50
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered empty.	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:34:46

US3292127

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

Form: Exposure

Generated On: 09 Jun 2021 16:21:43

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered 'mRNA-1273'	System	28 Jan 2021 23:34:46
DataPoint set to visible.	System	28 Jan 2021 23:34:27

US3292127

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

Form: Exposure

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:58:50
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '28 Jan 2021'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:34:46

US3292127

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

Form: Exposure

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:58:50
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '15:23'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:34:46

US3292127

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

Form: Exposure

Generated On: 09 Jun 2021 16:21:43

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered '28 Jan 2021 15:23'	System	28 Jan 2021 23:34:46

US3292127

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

Form: Exposure

Generated On: 09 Jun 2021 16:21:43

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:58:50
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered 'Left Arm (LEFT ARM)'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:34:46

US3292127

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

Form: Exposure

Generated On: 09 Jun 2021 16:21:43

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:58:50
User entered 'ONCE'	System	28 Jan 2021 23:34:46

US3292127

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

Form: Exposure

Generated On: 09 Jun 2021 16:21:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered 'INTRAMUSCULAR'	System	28 Jan 2021 23:34:46

US3292127

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:43

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:59:00
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:33:44

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:59:00
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '28 Jan 2021'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:33:44

US3292127
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:21:43
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:59:00
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '14:50'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:33:44

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered '28 Jan 2021 14:50'	System	28 Jan 2021 23:33:44

US3292127

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:21:43

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:59:05
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:40
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:34:11

US3292127

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:21:43

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:59:05
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:40
User entered '28 Jan 2021'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:34:11

US3292127

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:59:05
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:40
User entered '14:26'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:34:11

US3292127

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:21:43

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered '28 Jan 2021 14:26'	System	28 Jan 2021 23:34:11

US3292127

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

Form: Continuing

Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:59:10
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 23:35:25

US3292127
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered '1'	System	28 Jan 2021 23:35:25

US3292127
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:03:09
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	08 Feb 2021 20:13:29

US3292127
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:03:09
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '5 Feb 2021'	Gerardo Pena (b) (4) (b) (4)	08 Feb 2021 20:13:29

US3292127
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:03:09
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered 'Contact Made (CONTACT MADE)'	Gerardo Pena (b) (4) (b) (4)	08 Feb 2021 20:13:29

US3292127
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:03:09
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
User entered empty.	Gerardo Pena (b) (4)	08 Feb 2021 20:13:29

US3292127

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:03:28
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	08 Feb 2021 20:13:38

US3292127
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered '1'	System	08 Feb 2021 20:13:38

US3292127
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43

OLD29 Placebo Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered '1'	System	08 Feb 2021 20:13:38
DataPoint set to visible.	System	08 Feb 2021 20:13:38

US3292127
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:21:43

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:00:38
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Feb 2021 16:52:42

US3292127
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:21:43

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:00:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	03 Mar 2021 14:12:23
User entered '26 Feb 2021'	(b) (4), (b) (6)	27 Feb 2021 16:52:42

US3292127
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:00:38
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	27 Feb 2021 16:52:42

US3292127
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:21:43
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered 'OLD29'	System	27 Feb 2021 16:52:42

US3292127
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:21:43
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User accepted default value 'Pre-Dose (PREDOSE)'		27 Feb 2021 16:54:03

US3292127
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:21:43
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:07:40
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Feb 2021 16:54:03

US3292127
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:21:43
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:07:40
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered '26 Feb 2021'	(b) (4), (b) (6)	27 Feb 2021 16:54:03

US3292127
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:07:40
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered '13:03'	(b) (4) (b) (4), (b) (6)	27 Feb 2021 16:54:03

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered '26 Feb 2021 13:03'	System	27 Feb 2021 16:54:03

US3292127
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:21:43

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:07:40
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered '36.9' C	(b) (4), (b) (6)	27 Feb 2021 16:54:03

US3292127
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:21:43

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:07:40
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	03 Mar 2021 14:12:23
User entered 'Oral (Oral)'	(b) (4), (b) (6)	27 Feb 2021 16:54:03

US3292127
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:21:43
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:07:40
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered empty.	(b) (4), (b) (6)	27 Feb 2021 16:54:03

US3292127
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:21:43

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:07:40
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered '79'	(b) (4), (b) (6)	27 Feb 2021 16:54:03

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered 'bpm'	System	27 Feb 2021 16:54:03

US3292127
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:21:43
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:07:40
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered '12'	(b) (4), (b) (6)	27 Feb 2021 16:54:03

US3292127
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:21:43
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered 'breaths/min'	System	27 Feb 2021 16:54:03

US3292127
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:21:43

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:07:40
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	03 Mar 2021 14:12:23
User entered '151'	(b) (4), (b) (6)	27 Feb 2021 16:54:03

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered 'mmHg'	System	27 Feb 2021 16:54:03

US3292127
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:21:43
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:07:40
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered '76'	(b) (4), (b) (6)	27 Feb 2021 16:54:03

US3292127
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:21:43
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered 'mmHg'	System	27 Feb 2021 16:54:03

US3292127
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:21:43
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User accepted default value 'Post-Dose (POSTDOSE)'		27 Feb 2021 16:54:44

US3292127
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:21:43
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:07:40
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Feb 2021 16:54:44

US3292127
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:21:43
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:07:40
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	27 Feb 2021 16:54:44

US3292127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:07:40
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	03 Mar 2021 14:12:23
User entered '14:30'	(b) (4), (b) (6)	27 Feb 2021 16:54:44

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered '26 Feb 2021 14:30'	System	27 Feb 2021 16:54:44

US3292127
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:21:43

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:07:40
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	03 Mar 2021 14:12:23
User entered '36.2' C	(b) (4), (b) (6)	27 Feb 2021 16:54:44

US3292127
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:21:43

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:07:40
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	03 Mar 2021 14:12:23
User entered 'Oral (Oral)'	(b) (4), (b) (6)	27 Feb 2021 16:54:44

US3292127
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:21:43
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:07:40
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Feb 2021 16:54:44

US3292127
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:21:43
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:07:40
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	03 Mar 2021 14:12:23
User entered '80'	(b) (4), (b) (6)	27 Feb 2021 16:54:44

US3292127
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:21:43
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered 'bpm'	System	27 Feb 2021 16:54:44

US3292127
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:21:43
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:07:40
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered '16'	(b) (4), (b) (6)	27 Feb 2021 16:54:44

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered 'breaths/min'	System	27 Feb 2021 16:54:44

US3292127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:07:40
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered '150'	(b) (4) (b) (4), (b) (6)	27 Feb 2021 16:54:44

US3292127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:21:43

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered 'mmHg'	System	27 Feb 2021 16:54:44

US3292127
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:21:43
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:07:40
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered '96'	(b) (4) (b) (4), (b) (6)	27 Feb 2021 16:54:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered 'mmHg'	System	27 Feb 2021 16:54:44

US3292127
Folder: OL-D29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:21:43

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:08:05
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Feb 2021 16:54:54

US3292127
Folder: OL-D29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:21:43
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:08:05
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered '26 Feb 2021'	(b) (4), (b) (6)	27 Feb 2021 16:54:54

US3292127
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:21:43

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:08:30
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Feb 2021 16:55:09

US3292127
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:21:43

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:08:30
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	03 Mar 2021 14:12:23
User entered empty.	(b) (4), (b) (6)	27 Feb 2021 16:55:09

US3292127

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:21:43

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)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:08:30
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	03 Mar 2021 14:12:23
User entered empty.	(b) (4), (b) (6)	27 Feb 2021 16:55:09

US3292127
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:21:43

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered 'mRNA-1273'	System	27 Feb 2021 16:55:09
DataPoint set to visible.	System	08 Feb 2021 20:13:38

US3292127
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:08:30
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered '26 Feb 2021'	(b) (4), (b) (6)	27 Feb 2021 16:55:09

US3292127

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:08:30
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	03 Mar 2021 14:12:23
User entered '14:00'	(b) (4), (b) (6)	27 Feb 2021 16:55:09

US3292127
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:21:43
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered '26 Feb 2021 14:00'	System	27 Feb 2021 16:55:09

US3292127
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:21:43
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:08:30
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	03 Mar 2021 14:12:23
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	27 Feb 2021 16:55:09

US3292127
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:21:43

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:08:30
User entered 'ONCE'	System	27 Feb 2021 16:55:09

US3292127
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:21:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered 'INTRAMUSCULAR'	System	27 Feb 2021 16:55:09

US3292127
Folder: OL-D29 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:08:39
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Feb 2021 16:55:12

US3292127
Folder: OL-D29 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered '1'	System	27 Feb 2021 16:55:12

US3292127
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:10:10
User entered 'Yes (Y)'		07 Mar 2021 17:11:40

US3292127
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:10:10
User entered '5 Mar 2021'		07 Mar 2021 17:11:40

US3292127
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:10:10
User entered 'Contact Made (CONTACT MADE)'		07 Mar 2021 17:11:40

US3292127
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:21:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:10:10
User entered empty.		07 Mar 2021 17:11:40

US3292127
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:10:31
User entered 'Yes (Y)'		07 Mar 2021 17:11:44

US3292127
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:21:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered '1'	System	07 Mar 2021 17:11:44

US3292127
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:21:43

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:34:24
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:15:35
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	29 Mar 2021 19:08:59

US3292127

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:21:43

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:34:24
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
User entered '26 Mar 2021'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:08:59

US3292127
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:34:24
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
User entered 'Clinic (Clinic)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:08:59

US3292127
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:21:43
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered 'OLD57'	System	29 Mar 2021 19:08:59

US3292127
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:34:28
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:09:04

US3292127
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:34:28
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:09:04

US3292127
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:34:28
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:09:04

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered empty.	System	29 Mar 2021 19:09:04

US3292127
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:34:28
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:09:04

US3292127
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:34:28
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:09:04

US3292127
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:34:28
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:09:04

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:34:28
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:09:04

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered empty.	System	29 Mar 2021 19:09:04

FDA-CBER-2022-1614-1667019

US3292127
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:34:28
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:09:04

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered empty.	System	29 Mar 2021 19:09:04

US3292127
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:34:28
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:09:04

US3292127
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered empty.	System	29 Mar 2021 19:09:04

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:34:28
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:09:04

US3292127
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered empty.	System	29 Mar 2021 19:09:04

US3292127
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16

US3292127
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:21:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16

US3292127
Folder: OL-D57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:21:43

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:34:33
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:09:08

US3292127

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:21:43

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:34:33
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:09:08

US3292127

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:21:43

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:34:41
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:09:18

US3292127
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:21:43
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:34:41
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
User entered '26 Mar 2021'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:09:18

US3292127
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:21:43
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:34:41
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	08 Apr 2021 16:15:35
User entered '12:52'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:09:18

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:16
User entered '26 Mar 2021 12:52'	System	29 Mar 2021 19:09:18

US3292127
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 16:21:43

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:11:09
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
User entered 'Yes (Y)'	(b) (4) Antonio Gutierrez (b) (4)	02 Dec 2020 21:44:04

US3292127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

AEID

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:39:07
Reviewed for Safety.		11 Dec 2020 15:47:21
Un-reviewed for Safety.		11 Dec 2020 15:44:37
Reviewed for Safety.		03 Dec 2020 16:55:25
User entered 'USA-US072-2020-mRNA-1273-P301000015'	System	03 Dec 2020 16:54:54
User entered 'New'	(b) (4), (b) (6)	03 Dec 2020 16:54:54

(b

US3292127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:32:39
User closed query 'PV Query: The subject had vascular damage to right calf. Please assess if it meets separate AE/SAE reporting criteria and report accordingly in EDC.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 01:32:19
Query 'PV Query: The subject had vascular damage to right calf. Please assess if it meets separate AE/SAE reporting criteria and report accordingly in EDC.' answered with 'AE added' (Site from Safety).	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:32:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 18:13:57
User opened query 'PV Query: The subject had vascular damage to right calf. Please assess if it meets separate AE/SAE reporting criteria and report accordingly in EDC.' (Site from Safety).		09 Dec 2020 20:34:34
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Road traffic accident, LLT: Motor vehicle accident - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 21:52:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 21:52:52
Data point term sent to Coder	System	02 Dec 2020 21:51:59
User entered 'Motor Vehicle Accident'	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

US3292127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:15:03
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

US3292127
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:21:43

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 18:15:07
User entered 'No (N)'	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

US3292127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:15:13
User entered 'No (N)'	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

US3292127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:15:16
User entered '25 Nov 2020'	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

US3292127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:49
User entered empty.	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

US3292127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 21:51:52

US3292127
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:21:43
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:12:58
DataPoint Un-verified.		27 Feb 2021 16:57:34
User entered 'No (N)' reason for change: Data Entry Error		27 Feb 2021 16:57:34
DataPoint Verified.		16 Dec 2020 18:15:27
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

US3292127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
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) (4), (b) (6)	25 Mar 2021 15:08:27
DataPoint Verified.		09 Mar 2021 15:13:00
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).		27 Feb 2021 17:01:03
User entered '25 Nov 2020' reason for change: Data Entry Error		27 Feb 2021 16:57:34
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).		16 Dec 2020 13:40:09
User entered empty.	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:39:14
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.' canceled (Site from Safety).		16 Dec 2020 13:39:35
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).		09 Dec 2020 20:33:47
User entered empty.	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

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Folder: Adverse Events

Form: Adverse Events (1)

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AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 21:51:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

Severity

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
Query 'PV Query: Please confirm the severity, since the event lead to hospitalization.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:03:31
DataPoint Verified.		16 Dec 2020 18:15:32
User opened query 'PV Query: Please confirm the severity, since the event lead to hospitalization.' (Site from Safety).		16 Dec 2020 16:00:19
User entered 'Grade 3/Severe (Grade 3/Severe)'	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:15:44
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

US3292127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:57
User entered '0'	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

US3292127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:59
User entered '0'	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

US3292127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User closed query 'Per CDM re-query: Response noted; However Please provide the discharge date once it is available. Please leave the query open till an update made else respond to clarify. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:57:08
Query 'Per CDM re-query: Response noted; However Please provide the discharge date once it is available. Please leave the query open till an update made else respond to clarify. Thank you' answered with 'done' (Site from DM).		09 Apr 2021 19:32:57
DataPoint Verified.		16 Dec 2020 18:16:05
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).		16 Dec 2020 08:31:58
User opened query 'Per CDM re-query: Response noted; However Please provide the discharge date once it is available. Please leave the query open till an update made else respond to clarify. Thank you' (Site from DM).		16 Dec 2020 08:31:55
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 with 'Admission date is present. Patient remains hospitalized. Not in ICU' (Site from System).	Antonio Gutierrez (b) (4)	02 Dec 2020 21:53:12
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	02 Dec 2020 21:51:52
User entered '1'	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:18:07
User entered '25 Nov 2020'	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 20:29:07
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacte and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).		14 Apr 2021 14:47:15
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).		14 Apr 2021 14:46:20
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Sent 14:30 central on 13APR21.' (Site from Safety).	Antonio Gutierrez (b) (4)	13 Apr 2021 19:30:56
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'provided' (Site from Safety).	Antonio Gutierrez (b) (4)	13 Apr 2021 18:29:51
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 19:32:22
User entered '04 Dec 2020' reason for change: Data Entry Error		09 Apr 2021 19:32:22
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacte and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).		05 Mar 2021 14:13:30
DataPoint Verified.		18 Jan 2021 19:06:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'PV Query: Please provide the hospital discharge date when available.' canceled (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 20:40:36
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).		09 Dec 2020 20:35:35
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).		09 Dec 2020 20:35:26
User entered empty.	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:06:02
User entered 'No (N)'	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

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Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:21:43

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:06:43
User entered empty.	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:21:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:12:16
User entered '0'	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

US3292127
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:21:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:12:19
User entered '0'	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:12:21
User entered '0'	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:16:43
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' canceled (Site from Safety).		16 Dec 2020 13:39:20
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 16:58:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Dec 2020 16:58:56
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Antonio Gutierrez (b) (4)	10 Dec 2020 16:58:56
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 18:12:13
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 21:51:52
User entered empty.	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

US3292127
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:21:43
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:16:45
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' canceled (Site from Safety).		16 Dec 2020 13:39:22
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 16:58:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Dec 2020 16:58:56
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Antonio Gutierrez (b) (4)	10 Dec 2020 16:58:56
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 18:12:31
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 21:51:52
User entered empty.	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:16:47
User entered 'Not Applicable (NOT APPLICABLE)'	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:29:07
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	21 Apr 2021 19:38:29
User entered '0' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	21 Apr 2021 19:38:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:12:39
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Feb 2021 23:29:57
User entered '1' reason for change: New Information	Gerardo Pena (b) (4) (b) (4)	19 Feb 2021 23:29:57
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Dec 2020 21:51:52
User entered '0'	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

US3292127
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:21:43
Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:28:49
Query 'Per AE source, other action taken is "none". Please reconcile. ' canceled (Site from CRA).		22 Apr 2021 18:28:47
User opened query 'Per AE source, other action taken is "none". Please reconcile. ' (Site from CRA).		22 Apr 2021 16:54:18
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	21 Apr 2021 19:38:29
User entered '1' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	21 Apr 2021 19:38:29
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:12:42
User entered '0'	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:12:44
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety).		16 Dec 2020 13:40:22
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).		09 Dec 2020 20:34:06
User entered '0'	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
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) (4), (b) (6)	25 Mar 2021 15:08:36
DataPoint Verified.		09 Mar 2021 15:12:47
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).		27 Feb 2021 17:01:22
DataPoint Un-verified.		27 Feb 2021 16:57:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error		27 Feb 2021 16:57:34
DataPoint Verified.		16 Dec 2020 18:16:52
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).		16 Dec 2020 13:39:43
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

US3292127
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:21:43
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:12:54
User entered empty.	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

Narrative

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User closed query 'Per DM CLR: Narrative indicates that the subject underwent 3 surgeries to right calf. However, there are no corresponding Concomitant Procedures record that match the information. Please review and update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:00:32
User closed query 'Per DM CLR: Narrative indicates that the subject had Vascular Damage on Right Calf. However, there is no corresponding AE record that match the information. Please update to record the corresponding AE as appropriate. Otherwise, clarify.' (Site from DM).		15 Apr 2021 13:00:29
User closed query 'PV Query: Please provide any tests and results of SARS-CoV-2.' (Site from Safety).		14 Apr 2021 14:47:59
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).		14 Apr 2021 14:47:52
User closed query 'PV Query: Please specify the nature and circumstances that led to the accident?' (Site from Safety).		14 Apr 2021 14:47:36
User closed query 'PV Query: AE #1 and # 2: 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).		14 Apr 2021 14:47:28
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Sent to Moderna safety email account at 16:16 central on 13APR21' (Site from Safety).	Antonio Gutierrez (b) (4)	13 Apr 2021 21:16:29
Query 'Per DM CLR: Narrative indicates that the subject underwent 3 surgeries to right calf. However, there are no corresponding Concomitant Procedures record that match the information. Please review and update to record the procedures as appropriate. Otherwise, clarify.' answered with 'Con Procedures updated ' (Site from DM).	Antonio Gutierrez (b) (4)	13 Apr 2021 19:43:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

Narrative

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative indicates that the subject had Vascular Damage on Right Calf. However, there is no corresponding AE record that match the information. Please update to record the corresponding AE as appropriate. Otherwise, clarify.' answered with 'This corresponds to Right Calf Hematoma ' (Site from DM).	Antonio Gutierrez (b) (4)	13 Apr 2021 19:33:18
Query 'PV Query: AE #1 and # 2: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'No COVID testing noted in records received. ' (Site from Safety).	Antonio Gutierrez (b) (4)	13 Apr 2021 19:09:40
Query 'PV Query: Please provide any tests and results of SARS-CoV-2.' answered with 'No COVID testing noted in medical records received. ' (Site from Safety).	Antonio Gutierrez (b) (4)	13 Apr 2021 19:08:58
Query 'PV Query: Please specify the nature and circumstances that led to the accident?' answered with 'Subject was rear-ended at roughly 60-70mph. Was not at fault. ' (Site from Safety).	Antonio Gutierrez (b) (4)	13 Apr 2021 18:46:56
User opened query 'PV Query: AE #1 and # 2: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 14:14:47
User opened query 'Per DM CLR: Narrative indicates that the subject underwent 3 surgeries to right calf. However, there are no corresponding Concomitant Procedures record that match the information. Please review and update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM).		14 Jan 2021 07:44:19
User opened query 'Per DM CLR: Narrative indicates that the subject had Vascular Damage on Right Calf. However, there is no corresponding AE record that match the information. Please update to record the corresponding AE as appropriate. Otherwise, clarify.' (Site from DM).		14 Jan 2021 07:44:10
DataPoint Verified.		16 Dec 2020 18:14:56
User opened query 'PV Query: Please provide any tests and results of SARS-CoV-2.' (Site from Safety).		16 Dec 2020 16:00:36

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

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)	16 Dec 2020 13:40:26
User opened query 'PV Query: Please specify the nature and circumstances that led to the accident?' (Site from Safety).		09 Dec 2020 20:35:01
User entered 'Pt's sister called today to report that patient was in a car accident on 25Nov2020. Pt has been admitted to the hospital and remains admitted. Pt reportedly has vascular damage to his right calf. Pt has also reportedly undergone three surgeries to right calf, though specifics will be requested along with medical records. No plans for discharge at the moment. Will follow up once patient is stabilized and able to give a report to staff. Medical records will also be collected.'	Antonio Gutierrez (b) (4)	02 Dec 2020 21:51:52

US3292127
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:21:43
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	02 Dec 2020 21:51:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	02 Dec 2020 21:51:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:21:43

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	02 Dec 2020 21:51:52

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:11:51
Reviewed for Safety.		22 Feb 2021 15:02:48
Un-reviewed for Safety.		22 Feb 2021 15:02:39
User entered 'USA-US072-2020-mRNA-1273-P301000015' reason for change: Data Entry Error		22 Feb 2021 15:02:39
Reviewed for Safety.		01 Feb 2021 17:44:36
User entered 'USA-US072-2021-mRNA-1273-P301000012'		01 Feb 2021 17:44:26
User entered 'New'		01 Feb 2021 17:44:26

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:32:39
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal haemorrhages NEC, HLT: Non-site specific gastrointestinal haemorrhages, PT: Gastrointestinal haemorrhage, LLT: GI hemorrhage - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 20:10:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 20:10:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:30:02
User closed query 'Per MM, please specify the location of hemorrhage if possible ' (Site from DM).		15 Apr 2021 13:01:56
Data point term sent to Coder	System	13 Apr 2021 21:44:09
Query 'Per MM, please specify the location of hemorrhage if possible ' answered with 'added GI' (Site from DM).	Antonio Gutierrez (b) (4)	13 Apr 2021 21:43:34
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	13 Apr 2021 21:43:24
Coding entries removed.	Antonio Gutierrez (b) (4)	13 Apr 2021 21:43:24
User entered 'INTERNAL GI HEMORRHAGE - MOTOR VEHICAL ACCIDENT' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	13 Apr 2021 21:43:24
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:14:36
User coded data point as SOC: Vascular disorders, HLGT: Vascular haemorrhagic disorders, HLT: Haemorrhages NEC, PT: Internal haemorrhage, LLT: Internal hemorrhage - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 21:54:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 21:54:40
User closed query 'PV Query: Please provide the etiology or underlying cause of the event.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 15:02:11
Data point term sent to Coder	System	19 Feb 2021 23:32:09
Query 'PV Query: Please provide the etiology or underlying cause of the event.' answered with 'updated' (Site from Safety).	Gerardo Pena (b) (4) (b) (4)	19 Feb 2021 23:31:21
Coding entries removed.	Gerardo Pena (b) (4) (b) (4)	19 Feb 2021 23:31:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

Adverse event

Audit	User	Time (GMT)
User entered 'INTERNAL HEMORRHAGE - motor vehical accident' reason for change: Data Entry Error	Gerardo Pena (b) (4) (b) (4)	19 Feb 2021 23:31:11
User opened query 'Per MM, please specify the location of hemorrhage if possible ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 16:25:13
User opened query 'PV Query: Please provide the etiology or underlying cause of the event.' (Site from Safety).		05 Feb 2021 17:55:06
User coded data point as SOC: Vascular disorders, HLGT: Vascular haemorrhagic disorders, HLT: Haemorrhages NEC, PT: Internal haemorrhage, LLT: Internal hemorrhage - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Jan 2021 22:22:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Jan 2021 22:22:24
Data point term sent to Coder	System	29 Jan 2021 22:22:02
User entered 'Internal Hemorrhage'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

US3292127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:14:39
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

US3292127
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:21:43
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:14:42
User entered 'No (N)'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

US3292127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:14:45
User entered 'No (N)'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:32
User closed query 'PV Query: As per the discharge summary, the subject experienced symptoms of melena couple of days before presenting to hospital on 17 Dec 2020. As the event onset date should be the date when first signs and symptoms appeared and not when the event became serious, therefore please update the event onset date to the date when first signs and symptoms (dark stools) appeared. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:22:01
DataPoint Verified.		29 Apr 2021 12:54:18
Query 'PV Query: As per the discharge summary, the subject experienced symptoms of melena couple of days before presenting to hospital on 17 Dec 2020. As the event onset date should be the date when first signs and symptoms appeared and not when the event became serious, therefore please update the event onset date to the date when first signs and symptoms (dark stools) appeared. ' answered with 'Updated,' (Site from Safety).		28 Apr 2021 15:28:27
DataPoint Un-verified.		28 Apr 2021 15:15:58
Signature has been broken.		28 Apr 2021 15:15:58
User entered '13 Dec 2020' reason for change: New Information		28 Apr 2021 15:15:58
User opened query 'PV Query: As per the discharge summary, the subject experienced symptoms of melena couple of days before presenting to hospital on 17 Dec 2020. As the event onset date should be the date when first signs and symptoms appeared and not when the event became serious, therefore please update the event onset date to the date when first signs and symptoms (dark stools) appeared. ' (Site from Safety).		28 Apr 2021 01:26:30
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:30:06
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	13 Apr 2021 21:44:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '17 Dec 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	13 Apr 2021 21:44:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:14:53
User entered '8 Dec 2020'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:14:58
User entered empty.	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 22:21:06

US3292127
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:21:43
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:15:33
User entered 'No (N)'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

US3292127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify "The subject report that surgery finally controlled the bleed on 15 Dec 2020 ". The event stop date is 11 Jan 2021 Was there a procedure performed on 15 dec 2020 because as per the discharge summary, the subject was still experiencing GI hemorrhage after 15 Dec2020.	(b) (4), (b) (6)	29 Apr 2021 13:24:00
' (Site from Safety). Query 'PV Query: Please clarify "The subject report that surgery finally controlled the bleed on 15 Dec 2020 ". The event stop date is 11 Jan 2021. Was there a procedure performed on 15 dec 2020 because as per the discharge summary, the subject was still experiencing GI hemorrhage after 15 Dec2020.		28 Apr 2021 15:28:52
' answered with 'Date updated in narrative summary. ' (Site from Safety). User opened query 'PV Query: Please clarify "The subject report that surgery finally controlled the bleed on 15 Dec 2020 ". The event stop date is 11 Jan 2021. Was there a procedure performed on 15 dec 2020 because as per the discharge summary, the subject was still experiencing GI hemorrhage after 15 Dec2020.		28 Apr 2021 01:26:42
' (Site from Safety). User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User closed query 'Per Narrative, End date is 15Dec2020. Please review and reconcile. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 20:30:19
DataPoint Verified.		16 Apr 2021 20:30:18
Query 'Per Narrative, End date is 15Dec2020. Please review and reconcile. ' answered with 'As per medical records, patient's historical record is incorrect and narrative will need to be updated based on records received.' (Site from CRA).	Antonio Gutierrez (b) (4)	13 Apr 2021 22:15:56
User opened query 'Per Narrative, End date is 15Dec2020. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 18:08:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	09 Mar 2021 18:08:30
DataPoint Verified.		09 Mar 2021 15:16:12
User entered '11 Jan 2021'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

US3292127
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:16:14
User entered empty.	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 22:21:06

US3292127
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:21:43
Severity

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:16:16
User entered 'Grade 3/Severe (Grade 3/Severe)'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

US3292127
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:21:43

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:16:18
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

US3292127
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:21:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:16:20
User entered '0'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

US3292127
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:21:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:16:23
User entered '0'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

US3292127
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:21:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:16:26
User entered '1'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User closed query 'PV Query: The patient stated that 'a surgery finally controlled his bleeding' on 15 Dec 2021, however the subject was re-admitted on 17 De 2021. Please confirm when the subject was re-hospitalized for internal GI hemorrhage. Also, please confirm the onset date of the event internal GI hemorrhage.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 14:57:48
Query 'PV Query: The patient stated that 'a surgery finally controlled his bleeding' on 15 Dec 2021, however the subject was re-admitted on 17 Dec 2021 Please confirm when the subject was re-hospitalized for internal GI hemorrhage. Also, please confirm the onset date of the event internal GI hemorrhage.' answered with 'confirmed' (Site from Safety).		22 Apr 2021 21:21:22
DataPoint Verified.		22 Apr 2021 20:40:10
DataPoint Un-verified.		21 Apr 2021 18:14:18
User opened query 'PV Query: The patient stated that 'a surgery finally controlled his bleeding' on 15 Dec 2021, however the subject was re-admitted on 17 De 2021. Please confirm when the subject was re-hospitalized for internal GI hemorrhage. Also, please confirm the onset date of the event internal GI hemorrhage.' (Site from Safety).		19 Apr 2021 13:21:55
DataPoint Verified.		16 Apr 2021 20:30:32
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	13 Apr 2021 21:44:27
User entered '17 Dec 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	13 Apr 2021 21:44:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:16:37
User entered '8 Dec 2020'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:16:41
Query 'PV Query: Please submit the discharge summary for this hospitalization.' canceled (Site from Safety).		05 Mar 2021 14:18:55
User opened query 'PV Query: Please submit the discharge summary for this hospitalization.' (Site from Safety).		01 Mar 2021 14:45:58
User entered '11 Jan 2021'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:21:43
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:16:44
User entered 'No (N)'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:16:47
User entered empty.	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:21:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:16:49
User entered '0'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:16:52
User entered '0'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

US3292127
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:21:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:17:12
User entered '0'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:18:06
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:21:43
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:18:09
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
User closed query 'PV Query: As the subject received both the doses of IP before the start of the event, please update action taken from none to not applicable. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:24:07
DataPoint Verified.		29 Apr 2021 12:52:09
Query 'PV Query: As the subject received both the doses of IP before the start of the event, please updat action taken from none to not applicable. ' answered with 'Updated. ' (Site from Safety).		28 Apr 2021 15:29:43
DataPoint Un-verified.		28 Apr 2021 15:29:22
Signature has been broken.		28 Apr 2021 15:29:22
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error		28 Apr 2021 15:29:22
User opened query 'PV Query: As the subject received both the doses of IP before the start of the event, please update action taken from none to not applicable. ' (Site from Safety).		28 Apr 2021 01:26:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User closed query 'Per source, answer is None. Please reconcile. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:41:29
DataPoint Verified.		19 Apr 2021 17:41:27
Query 'Per source, answer is None. Please reconcile. ' answered with 'Reconciled' (Site from CRA).		19 Apr 2021 16:21:24
User entered 'None (NONE)' reason for change: Data Entry Error		19 Apr 2021 16:20:33
User opened query 'Per source, answer is None. Please reconcile. ' (Site from CRA).		16 Apr 2021 20:34:29
User closed query 'PV Query: As the subject received both doses of placebo prior to the onset of the event, please consider updating the action taken to Not Applicable.' (Site from Safety).		14 Apr 2021 14:48:39
Query 'PV Query: As the subject received both doses of placebo prior to the onset of the event, please consider updating the action taken to Not Applicable.' answered with 'updated' (Site from Safety).		13 Apr 2021 18:20:28

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 18:19:56
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error		13 Apr 2021 18:19:56
DataPoint Verified.		09 Mar 2021 15:18:14
User opened query 'PV Query: As the subject received both doses of placebo prior to the onset of the event, please consider updating the action taken to Not Applicable.' (Site from Safety).		05 Feb 2021 17:54:56
User entered 'None (NONE)'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:42:45
User closed query ' "Other Action Taken" in AE source still states "None". Please review and update EDC/Source accordingly.' (Site from CRA).		23 Apr 2021 13:42:34
Query ' "Other Action Taken" in AE source still states "None". Please review and update EDC/Source accordingly.' answered with 'Other Action Taken is answered with Concomitant Procedure. Please see note next to Other Action Taken as only one action can be selected. ' (Site from CRA).		22 Apr 2021 21:25:15
User opened query ' "Other Action Taken" in AE source still states "None". Please review and update EDC/Source accordingly.' (Site from CRA).		22 Apr 2021 16:57:43
User closed query 'Answer not present in AE source. Please reconcile.' (Site from CRA).		22 Apr 2021 16:57:43
Query 'Answer not present in AE source. Please reconcile.' answered with 'source has been corrected' (Site from CRA).		21 Apr 2021 21:19:38
DataPoint Un-verified.		21 Apr 2021 18:14:23
DataPoint Verified.		21 Apr 2021 18:14:13
User opened query 'Answer not present in AE source. Please reconcile.' (Site from CRA).		16 Apr 2021 20:33:27
User closed query 'Please provide answer in source.' (Site from CRA).		16 Apr 2021 20:33:27
Query 'Please provide answer in source.' answered with 'updated source ' (Site from CRA).	Antonio Gutierrez (b) (4)	13 Apr 2021 21:50:39
User opened query 'Please provide answer in source.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 15:20:09
DataPoint Un-verified.		09 Mar 2021 15:19:14
DataPoint Verified.		09 Mar 2021 15:18:49
User entered '0'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:42:43
User closed query '"Other Action Taken" in AE source still states "None". Please review and update EDC/Source accordingly. ' (Site from CRA).		23 Apr 2021 13:42:36
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).		23 Apr 2021 06:42:48
Query '"Other Action Taken" in AE source still states "None". Please review and update EDC/Source accordingly. ' answered with 'Other Action Taken is answered with Concomitant Procedure. Please see note next to Other Action Taken as only one action can be selected. ' (Site from CRA).		22 Apr 2021 21:25:17
User opened query '"Other Action Taken" in AE source still states "None". Please review and update EDC/Source accordingly. ' (Site from CRA).		22 Apr 2021 16:56:40
User closed query 'Answer not present in AE source. Please reconcile.' (Site from CRA).		22 Apr 2021 16:56:40
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'conmeds have been added' (Site from DM).		21 Apr 2021 22:06:42
Query 'Answer not present in AE source. Please reconcile.' answered with 'answer has been provided' (Site from CRA).		21 Apr 2021 22:06:22
DataPoint Un-verified.		21 Apr 2021 18:14:24
DataPoint Verified.		21 Apr 2021 18:14:13
User opened query 'Answer not present in AE source. Please reconcile.' (Site from CRA).		16 Apr 2021 20:33:34
User closed query 'Please provide answer in source.' (Site from CRA).		16 Apr 2021 20:33:34
Query 'Please provide answer in source.' answered with 'updated source ' (Site from CRA).	Antonio Gutierrez (b) (4)	13 Apr 2021 21:50:45

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

Concomitant Medication

Audit	User	Time (GMT)
User opened query 'Please provide answer in source.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 15:20:15
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).		16 Feb 2021 11:19:47
User entered '1'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:21:43

Concomitant Procedure

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE. Please review and update to record the treatment procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 11:16:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:27
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE. Please review and update to record the treatment procedure as appropriate. Otherwise, clarify.' answered with 'added' (Site from DM).		22 Apr 2021 21:40:28
User closed query 'Answer not present in AE source. Please reconcile.' (Site from CRA).		22 Apr 2021 16:55:56
Query 'Answer not present in AE source. Please reconcile.' answered with 'answer has been provided' (Site from CRA).		21 Apr 2021 22:06:29
DataPoint Un-verified.		21 Apr 2021 18:14:26
DataPoint Verified.		21 Apr 2021 18:14:13
User opened query 'Answer not present in AE source. Please reconcile.' (Site from CRA).		16 Apr 2021 20:33:37
User closed query 'Please provide answer in source.' (Site from CRA).		16 Apr 2021 20:33:37
Query 'Please provide answer in source.' answered with 'updated source ' (Site from CRA).	Antonio Gutierrez (b) (4)	13 Apr 2021 21:50:55
User opened query 'Please provide answer in source.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 15:20:23
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE. Please review and update to record the treatment procedure as appropriate. Otherwise, clarify.' (Site from DM).		16 Feb 2021 11:19:54
User entered '1'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:20:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:20:36
User entered empty.	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

US3292127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

Narrative

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:32
User closed query 'PV Query: As per the discharge summary the subject was diagnosed with C6-C7 ligamentous injury, blunt injury to right lower extremity, right lower extremity hematoma, punctate laceration anterior scalp, severe prostatomegaly, left pleural effusion. Kindly report these as separate SAE/AE. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:24:12
DataPoint Verified.		29 Apr 2021 12:57:14
Query 'PV Query: As per the discharge summary the subject was diagnosed with C6-C7 ligamentous injury, blunt injury to right lower extremity, right lower extremity hematoma, punctate laceration anterior scalp, severe prostatomegaly, left pleural effusion. Kindly report these as separate SAE/AE. ' answered with 'Added.' (Site from Safety).		28 Apr 2021 16:07:16
User entered 'PATIENT WAS IN CLINIC FOR DECISION VISIT ON 28JAN2021 AND INFORMED STAFF THAT HE HAD BEEN HOSPITALIZED ONCE AGAIN FOLLOWING A RECENT HOSPITALIZATION FOR A PREVIOUSLY REPORTED SAE. PATIENT STATES THAT DOCTORS DISCOVERED INTERNAL BLEEDING AT TWO DIFFERENT SITES INTERNALLY. PATIENT CANNOT SPECIFY WHICH SITES. PATIENT WAS UNABLE TO DESCRIBE MEDICATIONS OR PROCEDURES COMPLETED. PATIENT STATES THAT SURGERY FINALLY CONTROLLED AND STOPPED THE BLEED ON 29DEC2020, BUT HE REMAINED HOSPITALIZED. MEDICAL RECORDS WILL BE REQUESTED ASAP.' reason for change: New Information		28 Apr 2021 15:28:06
DataPoint Un-verified.	(b) (4), (b) (6)	28 Apr 2021 15:26:29
Signature has been broken.		28 Apr 2021 15:26:29

Audit	User	Time (GMT)
User entered 'PATIENT WAS IN CLINIC FOR DECISION VISIT ON 28JAN2021 AND INFORMED STAFF THAT HE HAD BEEN HOSPITALIZED ONCE AGAIN FOLLOWING A RECENT HOSPITALIZATION FOR A PREVIOUSLY REPORTED SAE. PATIENT STATES THAT DOCTORS DISCOVERED INTERNAL BLEEDING AT TWO DIFFERENT SITES INTERNALLY. PATIENT CANNOT SPECIFY WHICH SITES. PATIENT WAS UNABLE TO DESCRIBE MEDICATIONS OR PROCEDURES COMPLETED. PATIENT STATES THAT SURGERY FINALLY CONTROLLED AND STOPPED THE BLEED ON 28DEC2020, BUT HE REMAINED HOSPITALIZED. MEDICAL RECORDS WILL BE REQUESTED ASAP.' reason for change: New Information	(b) (4), (b) (6)	28 Apr 2021 15:26:29
User opened query 'PV Query: As per the discharge summary the subject was diagnosed with C6-C7 ligamentous injury, blunt injury to right lower extremity, right lower extremity hematoma, punctate laceration anterior scalp, severe prostatomegaly, left pleural effusion. Kindly report these as separate SAE/AE. ' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 01:25:58
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:32:39
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments (exact surgical procedure name). 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)	23 Apr 2021 14:58:21
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments (exact surgical procedure name). 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 'added' (Site from Safety).		22 Apr 2021 21:40:39

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Did the subject have signs and symptoms? If so please provide, if not please report how the bleed was discovered.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:54:37
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		22 Apr 2021 13:54:33
Query 'PV Query: Did the subject have signs and symptoms? If so please provide, if not please report how the bleed was discovered.' answered with 'subject went to clinic due to lightheadedness ' (Site from Safety).		21 Apr 2021 22:03:54
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'labs sent to Safety email previously' (Site from Safety).		21 Apr 2021 21:35:30
Query 'Narrative not provided in source. Please reconcile. ' canceled (Site from CRA).		16 Apr 2021 20:34:03
DataPoint Verified.		16 Apr 2021 20:33:57
User closed query 'PV Query: Please provide the site of internal bleeding.' (Site from Safety).		14 Apr 2021 14:49:10
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).		14 Apr 2021 14:49:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

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 'As per medical records received, no COVID testing was noted as having being completed. ' (Site from Safety).	Antonio Gutierrez (b) (4)	13 Apr 2021 22:21:59
Query 'PV Query: Please provide the site of internal bleeding.' answered with 'GI added to AE name' (Site from Safety).	Antonio Gutierrez (b) (4)	13 Apr 2021 21:43:11
User opened query 'Narrative not provided in source. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 15:21:13
User opened query 'PV Query: Please provide the site of internal bleeding.' (Site from Safety).		01 Mar 2021 14:45:19
User opened query 'PV Query: Did the subject have signs and symptoms? If so please provide, if not please report how the bleed was discovered.' (Site from Safety).		05 Feb 2021 17:55:16
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		05 Feb 2021 17:54:47
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).		05 Feb 2021 17:54:39
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments (exact surgical procedure name). 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 Feb 2021 17:54:32

Narrative

Audit	User	Time (GMT)
User entered 'PATIENT WAS IN CLINIC FOR DECISION VISIT ON 28JAN2021 AND INFORMED STAFF THAT HE HAD BEEN HOSPITALIZED ONCE AGAIN FOLLOWING A RECENT HOSPITALIZATION FOR A PREVIOUSLY REPORTED SAE. PATIENT STATES THAT DOCTORS DISCOVERED INTERNAL BLEEDING AT TWO DIFFERENT SITES INTERNALLY. PATIENT CANNOT SPECIFY WHICH SITES. PATIENT WAS UNABLE TO DESCRIBE MEDICATIONS OR PROCEDURES COMPLETED. Patient states that surgery finally controlled and stopped the bleed on 15DEC2020, but he remained hospitalized. MEDICAL RECORDS WILL BE REQUESTED ASAP.' reason for change: New Information	Antonio Gutierrez (b) (4)	29 Jan 2021 22:23:00
User entered 'Patient was in clinic for Decision Visit on 28JAN2021 and informed staff that he had been hospitalized once again following a recent hospitalization for a previously reported SAE. Patient states that doctors discovered internal bleeding at two different sites internally. Patient cannot specify which sites. Patient was unable to describe medications or procedures completed. Medical records will be requested ASAP.'	Antonio Gutierrez (b) (4)	29 Jan 2021 22:21:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	29 Jan 2021 22:21:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	29 Jan 2021 22:21:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:21:43

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	29 Jan 2021 22:21:06

Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:21:43
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:43

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:32:39
User coded data point as SOC: Vascular disorders, HLGT: Vascular haemorrhagic disorders, HLT: Haemorrhages NEC, PT: Haematoma, LLT: Hematoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 03:47:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 03:47:51
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:21:39
Data point term sent to Coder		27 Feb 2021 17:04:17
User entered 'Right CALF HEMATOMA' reason for change: Data Entry Error		27 Feb 2021 17:04:11
User entered 'R Calf Hematoma'		27 Feb 2021 17:03:58

US3292127
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:21:43
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:21:41
User entered 'Yes (Y)'		27 Feb 2021 17:03:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:43

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:21:44
User entered 'No (N)'		27 Feb 2021 17:03:58

US3292127
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:21:43
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:21:48
User entered 'No (N)'		27 Feb 2021 17:03:58

US3292127
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:22:02
DataPoint Un-verified.		09 Mar 2021 15:22:00
DataPoint Verified.		09 Mar 2021 15:21:56
User entered '25 Nov 2020'		27 Feb 2021 17:03:58

US3292127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:22:05
User entered empty.		27 Feb 2021 17:03:58

US3292127
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:21:43

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User entered empty.	System	27 Feb 2021 17:03:58

US3292127
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:22:07
User entered 'No (N)'		27 Feb 2021 17:03:58

US3292127
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:21:43
If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:23:22
User entered '4 Jan 2021'		27 Feb 2021 17:03:58

US3292127
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:23:25
User entered empty.		27 Feb 2021 17:03:58

US3292127
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:21:43
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User entered empty.	System	27 Feb 2021 17:03:58

US3292127
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:21:43
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:23:27
User entered 'Grade 3/Severe (Grade 3/Severe)'		27 Feb 2021 17:03:58

US3292127
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:21:43
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:23:30
User entered 'No (N)'		27 Feb 2021 17:03:58

US3292127
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:21:43
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:24:04
User entered '0'		27 Feb 2021 17:03:58

US3292127
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:21:43
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:24:07
User entered '0'		27 Feb 2021 17:03:58

US3292127
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:21:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:24:10
User entered '0'		27 Feb 2021 17:03:58

US3292127
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:21:43

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:24:12
User entered empty.		27 Feb 2021 17:03:58

US3292127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:43

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:24:18
User entered empty.		27 Feb 2021 17:03:58

US3292127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:43

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:24:21
User entered empty.		27 Feb 2021 17:03:58

US3292127
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:21:43
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:24:25
User entered empty.		27 Feb 2021 17:03:58

US3292127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:43

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:24:28
User entered '0'		27 Feb 2021 17:03:58

US3292127
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:21:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:24:30
User entered '0'		27 Feb 2021 17:03:58

US3292127
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:21:43
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:24:33
User entered '0'		27 Feb 2021 17:03:58

US3292127
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:21:43
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:25:53
User entered 'Not Related (NOT RELATED)'		27 Feb 2021 17:03:58

US3292127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:43

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:25:55
User entered 'Not Related (NOT RELATED)'		27 Feb 2021 17:03:58

US3292127
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:21:43
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:25:58
User entered 'None (NONE)'		27 Feb 2021 17:03:58

US3292127
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:21:43
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:31
User entered '0'		27 Feb 2021 17:03:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:43

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:33
User entered '0'		27 Feb 2021 17:03:58

US3292127
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:21:43
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:27:23
User entered '1'		27 Feb 2021 17:03:58

US3292127
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:21:43
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:27:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		27 Feb 2021 17:03:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:28:18
User entered empty.		27 Feb 2021 17:03:58

US3292127
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:21:43
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:28:20
User entered empty.		27 Feb 2021 17:03:58

US3292127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:43

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User entered '0'	System	27 Feb 2021 17:03:58

US3292127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:21:43

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33
User entered '1'	System	27 Feb 2021 17:03:58

US3292127
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:21:43
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:33

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36

US3292127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:43

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:31:19
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Skin laceration, LLT: Skin tear - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 23:30:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 23:30:58
Data point term sent to Coder	System	27 Feb 2021 17:06:18
User entered 'Left Forearm Skin Tear'	(b) (4), (b) (6)	27 Feb 2021 17:05:55

US3292127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:43

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:31:24
User entered 'Yes (Y)'		27 Feb 2021 17:05:55

US3292127
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:21:43

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:31:27
User entered 'No (N)'		27 Feb 2021 17:05:55

US3292127
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:21:43
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:31:33
User entered 'No (N)'		27 Feb 2021 17:05:55

US3292127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:32:03
User entered '25 Nov 2020'		27 Feb 2021 17:05:55

US3292127
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:32:10
User entered empty.		27 Feb 2021 17:05:55

US3292127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:43

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User entered empty.	System	27 Feb 2021 17:05:55

US3292127
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:21:43
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:32:13
User entered 'No (N)'		27 Feb 2021 17:05:55

US3292127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:32:24
User entered '14 Dec 2020'		27 Feb 2021 17:05:55

US3292127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:32:28
User entered empty.		27 Feb 2021 17:05:55

US3292127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:43

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User entered empty.	System	27 Feb 2021 17:05:55

US3292127
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:21:43
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:33:33
User entered 'Grade 2/Moderate (Grade 2/Moderate)'		27 Feb 2021 17:05:55

US3292127
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:21:43
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:33:39
User entered 'No (N)'		27 Feb 2021 17:05:55

US3292127
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:21:43
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:33:55
User entered '0'		27 Feb 2021 17:05:55

US3292127
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:21:43
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:33:56
User entered '0'		27 Feb 2021 17:05:55

US3292127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:43

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:33:59
User entered '0'		27 Feb 2021 17:05:55

US3292127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:43

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:34:03
User entered empty.		27 Feb 2021 17:05:55

US3292127
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:21:43

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:34:05
User entered empty.		27 Feb 2021 17:05:55

US3292127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:43

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:34:08
User entered empty.		27 Feb 2021 17:05:55

US3292127
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:21:43
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:34:21
User entered empty.		27 Feb 2021 17:05:55

US3292127
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:21:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:34:23
User entered '0'		27 Feb 2021 17:05:55

US3292127
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:21:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:34:26
User entered '0'		27 Feb 2021 17:05:55

US3292127
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:21:43
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:34:28
User entered '0'		27 Feb 2021 17:05:55

US3292127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:43

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:34:51
User entered 'Not Related (NOT RELATED)'		27 Feb 2021 17:05:55

US3292127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:43

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:34:54
User entered 'Not Related (NOT RELATED)'		27 Feb 2021 17:05:55

US3292127
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:21:43
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:34:59
User entered 'None (NONE)'		27 Feb 2021 17:05:55

US3292127
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:21:43
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:35:08
User entered '1'		27 Feb 2021 17:05:55

US3292127
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:21:43
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:35:12
User entered '0'		27 Feb 2021 17:05:55

US3292127
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:21:43
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:35:16
User entered '0'		27 Feb 2021 17:05:55

US3292127
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:21:43
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:35:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		27 Feb 2021 17:05:55

US3292127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:35:21
User entered empty.		27 Feb 2021 17:05:55

US3292127
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:21:43
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:35:25
User entered empty.		27 Feb 2021 17:05:55

US3292127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:43

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User entered '0'	System	27 Feb 2021 17:05:55

US3292127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:43

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36
User entered '1'	System	27 Feb 2021 17:05:55

US3292127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:21:43

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:57:36

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41

US3292127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:21:43

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:20
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Post-traumatic pain, LLT: Post-traumatic pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Apr 2021 20:01:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Apr 2021 20:01:47
Data point term sent to Coder	System	27 Apr 2021 18:53:12
User entered 'General localized pain secondary to MVA'	(b) (4), (b) (6)	27 Apr 2021 18:52:31

US3292127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:21:43

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered 'Yes (Y)'		27 Apr 2021 18:52:31

US3292127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:21:43

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered 'No (N)'		27 Apr 2021 18:52:31

US3292127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:21:43

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered 'No (N)'		27 Apr 2021 18:52:31

US3292127
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered '25 Nov 2020'		27 Apr 2021 18:52:31

US3292127
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered empty.		27 Apr 2021 18:52:31

US3292127
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 16:21:43

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User entered empty.	System	27 Apr 2021 18:52:31

US3292127
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 16:21:43
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered 'No (N)'		27 Apr 2021 18:52:31

US3292127
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 16:21:43
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered '04 Jan 2021'		27 Apr 2021 18:52:31

US3292127
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered empty.		27 Apr 2021 18:52:31

US3292127
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 16:21:43

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User entered empty.	System	27 Apr 2021 18:52:31

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered 'Grade 2/Moderate (Grade 2/Moderate)'		27 Apr 2021 18:52:31

US3292127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:21:43

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered 'No (N)'		27 Apr 2021 18:52:31

US3292127
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 16:21:43
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered '0'		27 Apr 2021 18:52:31

US3292127
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 16:21:43
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered '0'		27 Apr 2021 18:52:31

US3292127
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 16:21:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered '0'		27 Apr 2021 18:52:31

US3292127
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 16:21:43

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered empty.		27 Apr 2021 18:52:31

US3292127
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 16:21:43
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered empty.		27 Apr 2021 18:52:31

US3292127
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 16:21:43
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered empty.		27 Apr 2021 18:52:31

US3292127
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 16:21:43

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered empty.		27 Apr 2021 18:52:31

US3292127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:21:43

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered '0'		27 Apr 2021 18:52:31

US3292127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:21:43

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered '0'		27 Apr 2021 18:52:31

US3292127
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 16:21:43
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered '0'		27 Apr 2021 18:52:31

US3292127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:21:43

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:20
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 16:07:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Apr 2021 16:07:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Apr 2021 16:07:42
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 18:52:31
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 18:52:31

US3292127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:21:43

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:20
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 16:07:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Apr 2021 16:07:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Apr 2021 16:07:42
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 18:52:31
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 18:52:31

US3292127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:21:43

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:20
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 22:24:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Apr 2021 22:24:47
User entered 'None (NONE)' reason for change: New Information	(b) (4), (b) (6)	27 Apr 2021 22:24:47
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 18:52:31
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 18:52:31

US3292127
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 16:21:43
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered '0'		27 Apr 2021 18:52:31

US3292127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:21:43

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered '1'		27 Apr 2021 18:52:31

US3292127
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 16:21:43
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered '0'		27 Apr 2021 18:52:31

US3292127
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 16:21:43
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		27 Apr 2021 18:52:31

US3292127
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 16:21:43
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered empty.		27 Apr 2021 18:52:31

US3292127
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 16:21:43
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:20
User entered 'General localized pain due to motor vehicle accident'		27 Apr 2021 18:52:31

US3292127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:21:43

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User entered '0'	System	27 Apr 2021 18:52:31

US3292127
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 16:21:43
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41
User entered '1'	System	27 Apr 2021 18:52:31

US3292127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:21:43

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:41

US3292127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:43

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:22
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Site specific injuries NEC, PT: Limb injury, LLT: Leg injury - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Apr 2021 19:29:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Apr 2021 19:29:28
Data point term sent to Coder	System	28 Apr 2021 16:03:25
User entered 'Blunt injury to RLE'	(b) (4), (b) (6)	28 Apr 2021 16:02:33

US3292127
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 16:21:43
Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered 'Yes (Y)'		28 Apr 2021 16:02:33

US3292127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:43

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered 'No (N)'		28 Apr 2021 16:02:33

Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 16:21:43
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered 'No (N)'		28 Apr 2021 16:02:33

US3292127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered '25 Nov 2020'		28 Apr 2021 16:02:33

US3292127
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered empty.		28 Apr 2021 16:02:33

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 16:02:33

US3292127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered 'Yes (Y)'		28 Apr 2021 16:02:33

US3292127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered empty.		28 Apr 2021 16:02:33

US3292127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered empty.		28 Apr 2021 16:02:33

US3292127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:43

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 16:02:33

US3292127
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 16:21:43

Severity

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered 'Grade 3/Severe (Grade 3/Severe)'		28 Apr 2021 16:02:33

US3292127
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 16:21:43
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered 'No (N)'		28 Apr 2021 16:02:33

US3292127
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 16:21:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered '0'		28 Apr 2021 16:02:33

US3292127
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 16:21:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered '0'		28 Apr 2021 16:02:33

US3292127
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 16:21:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered '0'		28 Apr 2021 16:02:33

US3292127
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 16:21:43

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered empty.		28 Apr 2021 16:02:33

US3292127
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 16:21:43
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered empty.		28 Apr 2021 16:02:33

US3292127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:43

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered empty.		28 Apr 2021 16:02:33

US3292127
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 16:21:43

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered empty.		28 Apr 2021 16:02:33

US3292127
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 16:21:43

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered '0'		28 Apr 2021 16:02:33

US3292127
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 16:21:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered '0'		28 Apr 2021 16:02:33

US3292127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:43

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered '0'		28 Apr 2021 16:02:33

US3292127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:43

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:22
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 16:54:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Apr 2021 16:54:40
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	29 Apr 2021 16:54:40
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 16:02:33
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 16:02:33

US3292127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:43

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:22
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 16:54:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Apr 2021 16:54:40
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	29 Apr 2021 16:54:40
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 16:02:33
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 16:02:33

US3292127
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 16:21:43
Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:22
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 16:54:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Apr 2021 16:54:40
User entered 'None (NONE)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	29 Apr 2021 16:54:40
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 16:02:33
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 16:02:33

US3292127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:43

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered '0'		28 Apr 2021 16:02:33

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered '0'		28 Apr 2021 16:02:33

FDA-CBER-2022-1614-1667254

US3292127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:43

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered '1'	(b) (4), (b) (6)	28 Apr 2021 16:02:33

US3292127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:43

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'		28 Apr 2021 16:02:33

US3292127
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 16:21:43
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered empty.		28 Apr 2021 16:02:33

US3292127
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 16:21:43
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:22
User entered 'Secondary to MVA'		28 Apr 2021 16:02:33

US3292127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:43

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	28 Apr 2021 16:02:33

US3292127

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:21:43

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 16:02:33

US3292127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:43

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:24
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Ligament injury, LLT: Ligament injury - version MedDRA\\23.0.	Coder Import (b) (4)	28 Apr 2021 17:49:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Apr 2021 17:49:53
Data point term sent to Coder	System	28 Apr 2021 16:04:26
User entered 'C6-C7 Ligamentous Injury'	(b) (4), (b) (6)	28 Apr 2021 16:03:40

US3292127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:43

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered 'Yes (Y)'		28 Apr 2021 16:03:40

US3292127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:43

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered 'No (N)'		28 Apr 2021 16:03:40

US3292127
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 16:21:43
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered 'No (N)'		28 Apr 2021 16:03:40

US3292127
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered '25 Nov 2020'		28 Apr 2021 16:03:40

US3292127
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered empty.		28 Apr 2021 16:03:40

US3292127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:43

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 16:03:40

US3292127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered 'Yes (Y)'		28 Apr 2021 16:03:40

US3292127
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 16:21:43
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered empty.		28 Apr 2021 16:03:40

US3292127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered empty.		28 Apr 2021 16:03:40

US3292127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:43

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 16:03:40

US3292127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:43

Severity

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered 'Grade 3/Severe (Grade 3/Severe)'		28 Apr 2021 16:03:40

US3292127
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 16:21:43
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered 'No (N)'		28 Apr 2021 16:03:40

US3292127
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 16:21:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered '0'		28 Apr 2021 16:03:40

US3292127
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 16:21:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered '0'		28 Apr 2021 16:03:40

US3292127
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 16:21:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered '0'		28 Apr 2021 16:03:40

US3292127
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 16:21:43

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered empty.		28 Apr 2021 16:03:40

US3292127
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 16:21:43
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered empty.		28 Apr 2021 16:03:40

US3292127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:43

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered empty.		28 Apr 2021 16:03:40

US3292127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:43

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered empty.		28 Apr 2021 16:03:40

US3292127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:43

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered '0'		28 Apr 2021 16:03:40

US3292127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:43

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered '0'		28 Apr 2021 16:03:40

US3292127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:43

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered '0'		28 Apr 2021 16:03:40

US3292127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:43

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:24
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 16:54:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Apr 2021 16:54:57
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	29 Apr 2021 16:54:57
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 16:03:40
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 16:03:40

US3292127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:43

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:24
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 16:54:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Apr 2021 16:54:57
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	29 Apr 2021 16:54:57
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 16:03:40
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 16:03:40

US3292127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:43

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:24
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 16:54:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Apr 2021 16:54:57
User entered 'None (NONE)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	29 Apr 2021 16:54:57
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 16:03:40
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 16:03:40

US3292127
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 16:21:43

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered '1'		28 Apr 2021 16:03:40

US3292127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:43

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered '0'		28 Apr 2021 16:03:40

US3292127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:43

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered '0'		28 Apr 2021 16:03:40

US3292127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:43

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'		28 Apr 2021 16:03:40

US3292127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered empty.		28 Apr 2021 16:03:40

US3292127
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 16:21:43
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:24
User entered 'Secondary to MVA'		28 Apr 2021 16:03:40

US3292127
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 16:21:43
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	28 Apr 2021 16:03:40

US3292127

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:21:43

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 16:03:40

US3292127

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:43

AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55

US3292127

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:43

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:25
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Skin laceration, LLT: Scalp laceration - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Apr 2021 18:24:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Apr 2021 18:24:39
Data point term sent to Coder	System	28 Apr 2021 16:05:26
User entered 'Punctate Laceration anterior scalp'	(b) (4), (b) (6)	28 Apr 2021 16:04:47

US3292127
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:21:43
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:25
User entered 'Yes (Y)'		28 Apr 2021 16:04:47

US3292127

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:43

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:25
User entered 'No (N)'		28 Apr 2021 16:04:47

US3292127
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:21:43
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:25
User entered 'No (N)'		28 Apr 2021 16:04:47

US3292127

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:25
User entered '25 Nov 2020'		28 Apr 2021 16:04:47

Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:25
User entered empty.		28 Apr 2021 16:04:47

US3292127

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:43

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User entered empty.	System	28 Apr 2021 16:04:47

US3292127
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:21:43
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:25
User entered 'No (N)'		28 Apr 2021 16:04:47

US3292127

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:25
User entered '07 Jan 2021'		28 Apr 2021 16:04:47

US3292127
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:25
User entered empty.		28 Apr 2021 16:04:47

US3292127

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:43

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User entered empty.	System	28 Apr 2021 16:04:47

US3292127
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:21:43
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:25
User entered 'Grade 3/Severe (Grade 3/Severe)'		28 Apr 2021 16:04:47

US3292127
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:21:43
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:25
User entered 'No (N)'		28 Apr 2021 16:04:47

US3292127
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:21:43
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:25
User entered '0'		28 Apr 2021 16:04:47

US3292127
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:21:43
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:25
User entered '0'		28 Apr 2021 16:04:47

US3292127
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:21:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:25
User entered '0'		28 Apr 2021 16:04:47

US3292127
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:21:43

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:25
User entered empty.		28 Apr 2021 16:04:47

US3292127
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:21:43
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:25
User entered empty.		28 Apr 2021 16:04:47

US3292127
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:21:43
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:25
User entered empty.		28 Apr 2021 16:04:47

US3292127

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:43

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:25
User entered empty.		28 Apr 2021 16:04:47

US3292127
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:21:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:25
User entered '0'		28 Apr 2021 16:04:47

US3292127
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:21:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:25
User entered '0'		28 Apr 2021 16:04:47

US3292127
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:21:43
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:25
User entered '0'		28 Apr 2021 16:04:47

US3292127

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:43

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:25
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 16:55:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Apr 2021 16:55:28
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	29 Apr 2021 16:55:28
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 16:04:47
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 16:04:47

US3292127

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:43

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:25
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 16:55:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Apr 2021 16:55:28
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	29 Apr 2021 16:55:28
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 16:04:47
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 16:04:47

US3292127

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:43

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:25
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 16:55:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Apr 2021 16:55:28
User entered 'None (NONE)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	29 Apr 2021 16:55:28
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 16:04:47
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 16:04:47

US3292127
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:21:43

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:25
User entered '1'		28 Apr 2021 16:04:47

US3292127

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:43

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:25
User entered '0'		28 Apr 2021 16:04:47

US3292127
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:21:43
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:25
User entered '0'		28 Apr 2021 16:04:47

US3292127

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:43

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:25
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 16:04:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Apr 2021 16:04:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Apr 2021 16:04:58
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 16:04:47
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 16:04:47

Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:25
User entered empty.		28 Apr 2021 16:04:47

US3292127
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:21:43
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:25
User entered 'Secondary to MVA' reason for change: Data Entry Error		28 Apr 2021 16:04:58
User entered empty.		28 Apr 2021 16:04:47

US3292127
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:21:43
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User entered '0'	System	28 Apr 2021 16:04:47

US3292127
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:21:43
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55
User entered '1'	System	28 Apr 2021 16:04:47

US3292127

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:21:43

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:30:55

US3292127
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 16:21:43
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15

US3292127

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:43

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:28
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatomegaly, LLT: Prostatomegaly - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Apr 2021 16:41:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Apr 2021 16:41:19
Data point term sent to Coder	System	28 Apr 2021 16:06:27
User entered 'Sever prostatomegaly'	(b) (4), (b) (6)	28 Apr 2021 16:06:02

US3292127
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 16:21:43
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered 'Yes (Y)'		28 Apr 2021 16:06:02

US3292127
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 16:21:43
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered 'No (N)'		28 Apr 2021 16:06:02

US3292127

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:43

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered 'No (N)'		28 Apr 2021 16:06:02

US3292127

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered '25 Nov 2020'		28 Apr 2021 16:06:02

US3292127

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered empty.		28 Apr 2021 16:06:02

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User entered empty.	System	28 Apr 2021 16:06:02

US3292127

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered 'No (N)'		28 Apr 2021 16:06:02

US3292127

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered '01 Jan 2021'		28 Apr 2021 16:06:02

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered empty.		28 Apr 2021 16:06:02

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User entered empty.	System	28 Apr 2021 16:06:02

US3292127
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 16:21:43
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered 'Grade 3/Severe (Grade 3/Severe)'		28 Apr 2021 16:06:02

US3292127
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 16:21:43
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered 'No (N)'		28 Apr 2021 16:06:02

US3292127
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 16:21:43
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered '0'		28 Apr 2021 16:06:02

US3292127

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:43

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered '0'		28 Apr 2021 16:06:02

US3292127
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 16:21:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered '0'		28 Apr 2021 16:06:02

US3292127
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 16:21:43
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered empty.		28 Apr 2021 16:06:02

US3292127

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:43

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered empty.		28 Apr 2021 16:06:02

US3292127
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 16:21:43
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered empty.		28 Apr 2021 16:06:02

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered empty.		28 Apr 2021 16:06:02

US3292127
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 16:21:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered '0'		28 Apr 2021 16:06:02

US3292127
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 16:21:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered '0'		28 Apr 2021 16:06:02

US3292127
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 16:21:43
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered '0'		28 Apr 2021 16:06:02

US3292127

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:43

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:28
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 16:55:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Apr 2021 16:55:40
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	29 Apr 2021 16:55:40
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 16:06:02
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 16:06:02

US3292127

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:43

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:28
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 16:55:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Apr 2021 16:55:40
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	29 Apr 2021 16:55:40
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 16:06:02
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 16:06:02

Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 16:21:43
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered 'None (NONE)'		28 Apr 2021 16:06:02

US3292127
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 16:21:43
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered '1'		28 Apr 2021 16:06:02

US3292127
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 16:21:43
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered '0'		28 Apr 2021 16:06:02

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered '0'		28 Apr 2021 16:06:02

US3292127

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:21:43

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		28 Apr 2021 16:06:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered empty.		28 Apr 2021 16:06:02

US3292127
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 16:21:43
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:28
User entered 'Secondary to MVA'		28 Apr 2021 16:06:02

US3292127
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 16:21:43
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User entered '0'	System	28 Apr 2021 16:06:02

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15
User entered '1'	System	28 Apr 2021 16:06:02

FDA-CBER-2022-1614-1667365

US3292127
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 16:21:43
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:15

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06

US3292127

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:43

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:30
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pleural effusion, LLT: Pleural effusion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Apr 2021 16:41:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Apr 2021 16:41:19
Data point term sent to Coder	System	28 Apr 2021 16:07:28
User entered 'Left pleural Effusion'	(b) (4), (b) (6)	28 Apr 2021 16:06:50

US3292127

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:43

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered 'Yes (Y)'		28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered 'No (N)'		28 Apr 2021 16:06:50

US3292127

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:43

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered 'No (N)'		28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered '25 Nov 2020'		28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered empty.		28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User entered empty.	System	28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered 'No (N)'		28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered '08 Jan 2021'		28 Apr 2021 16:06:50

US3292127

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered empty.		28 Apr 2021 16:06:50

US3292127

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:43

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User entered empty.	System	28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered 'Grade 3/Severe (Grade 3/Severe)'		28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered 'No (N)'		28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered '0'		28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered '0'		28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered '0'		28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered empty.		28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered empty.		28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered empty.		28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered empty.		28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered '0'		28 Apr 2021 16:06:50

FDA-CBER-2022-1614-1667388

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered '0'		28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered '0'		28 Apr 2021 16:06:50

US3292127

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:43

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:30
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 16:55:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Apr 2021 16:55:52
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	29 Apr 2021 16:55:52
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 16:06:50
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:30
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 16:55:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Apr 2021 16:55:52
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	29 Apr 2021 16:55:52
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 16:06:50
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered 'None (NONE)'		28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered '1'		28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered '0'		28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered '0'		28 Apr 2021 16:06:50

US3292127

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:21:43

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:01:30
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 16:56:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Apr 2021 16:56:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	29 Apr 2021 16:56:10
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 16:06:50
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered empty.		28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:01:30
User entered 'Secondary to MVA'		28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User entered '0'	System	28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06
User entered '1'	System	28 Apr 2021 16:06:50

US3292127
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:21:43
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:16
User closed query 'Please add con meds from Pg. 3;Lines 3 through 6g and pg.4; lines 1 through 3' (Site from CRA).		23 Apr 2021 19:26:43
Query 'Please add con meds from Pg. 3;Lines 3 through 6g and pg.4; lines 1 through 3' answered wit 'added' (Site from CRA).		22 Apr 2021 21:18:38
User opened query 'Please add con meds from Pg. 3;Lines 3 through 6g and pg.4; lines 1 through 3' (Site from CRA).		20 Apr 2021 16:07:50
User closed query 'Please add conmeds ASPIRIN, TRAMADOL, and HYDROMORPHINE to con med CRF. ' (Site from CRA).		20 Apr 2021 16:07:50
Query 'Please add conmeds ASPIRIN, TRAMADOL, and HYDROMORPHINE to con med CRF. ' answered with 'updated' (Site from CRA).	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:28:53
User opened query 'Please add conmeds ASPIRIN, TRAMADOL, and HYDROMORPHINE to con med CRF. ' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 15:46:49
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:33:24
User entered 'Yes (Y)'		12 Aug 2020 17:22:31

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 17:25:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 17:25:07
Data point term sent to Coder	System	12 Aug 2020 17:24:27
User entered 'Vitamin D'	(b) (4), (b) (6)	12 Aug 2020 17:24:18

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:43

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4)	29 Apr 2021 17:25:19
	(b) (4), (b) (6)	
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).		29 Apr 2021 10:01:21
DataPoint Un-verified.	(b) (4), (b) (6)	27 Apr 2021 18:29:34
Signature has been broken.		27 Apr 2021 18:29:34
User entered 'Yes (Y)' reason for change: Data Entry Error		27 Apr 2021 18:29:34
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'Updated' (Site from DM).		27 Apr 2021 18:28:45
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 16:06:27
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'No (N)'		12 Aug 2020 17:24:18

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'Supplement'		12 Aug 2020 17:24:18

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:43

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
	(b) (4)	
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. ' canceled (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 03:45:11
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).		18 Sep 2020 03:43:41
DataPoint Verified.		27 Aug 2020 17:34:48
User entered '25'		12 Aug 2020 17:24:18

FDA-CBER-2022-1614-1667407

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:43

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:09
User closed query 'Per source, dose unit is milligrams. please review and reconcile. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:18:21
DataPoint Verified.		20 Apr 2021 15:18:18
Query 'Per source, dose unit is milligrams. please review and reconcile. ' answered with 'updated' (Site from CRA).	Dawn Killian (b) (4) (b) (4)	12 Apr 2021 19:05:17
Signature has been broken.	Dawn Killian (b) (4) (b) (4)	12 Apr 2021 19:05:13
User entered 'mg (mg)' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	12 Apr 2021 19:05:13
User opened query 'Per source, dose unit is milligrams. please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 15:43:31
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:40
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)	05 Oct 2020 11:40:06
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).	Dawn Killian (b) (4) (b) (4)	24 Sep 2020 16:01:38
DataPoint Un-verified.	Dawn Killian (b) (4) (b) (4)	24 Sep 2020 16:01:23
User entered 'ug (ug)' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	24 Sep 2020 16:01:23
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)	18 Sep 2020 03:45:16
DataPoint Verified.		27 Aug 2020 17:34:48
User entered 'mg (mg)'		12 Aug 2020 17:24:18

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered empty.		12 Aug 2020 17:24:18

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:43

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'once daily (QD)'		12 Aug 2020 17:24:18

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered empty.		12 Aug 2020 17:24:18

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:43

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'Oral (ORAL)'		12 Aug 2020 17:24:18

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered empty.		12 Aug 2020 17:24:18

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		14 Aug 2020 00:37:48
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 17:31:47
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 17:24:18
User entered 'un UNK 2010'	(b) (4), (b) (6)	12 Aug 2020 17:24:18

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered '0'		12 Aug 2020 17:24:18

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'Yes (Y)'		12 Aug 2020 17:24:18

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered empty.		12 Aug 2020 17:24:18

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'No (N)'		12 Aug 2020 17:24:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 17:24:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 17:24:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 17:24:18

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
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)	12 Aug 2020 17:27:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 17:27:05
Data point term sent to Coder	System	12 Aug 2020 17:26:28
User entered 'Lisinopril'	(b) (4), (b) (6)	12 Aug 2020 17:25:27

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:43

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:43:46
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
User closed query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual medical condition recorded in MH eCRF. Please review and confirm prophylaxis indication if appropriate. Update or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 11:40:23
Query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual medical condition recorded in MH eCRF. Please review and confirm prophylaxis indication if appropriate. Update or provide clarification. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	24 Sep 2020 16:01:55
DataPoint Un-verified.	Dawn Killian (b) (4) (b) (4)	24 Sep 2020 16:01:49
User entered 'No (N)' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	24 Sep 2020 16:01:49
User opened query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual medical condition recorded in MH eCRF. Please review and confirm prophylaxis indication if appropriate. Update or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 03:43:00
DataPoint Verified.		27 Aug 2020 17:34:48
User entered 'Yes (Y)'		12 Aug 2020 17:25:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'Hypertension'		12 Aug 2020 17:25:27

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:43

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered '20'		12 Aug 2020 17:25:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:43

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'mg (mg)'		12 Aug 2020 17:25:27

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered empty.		12 Aug 2020 17:25:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:43

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'once daily (QD)'		12 Aug 2020 17:25:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered empty.		12 Aug 2020 17:25:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:43

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'Oral (ORAL)'		12 Aug 2020 17:25:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered empty.		12 Aug 2020 17:25:27

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		14 Aug 2020 00:37:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 17:31:32
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 17:25:27
User entered 'un UNK 2013'	(b) (4), (b) (6)	12 Aug 2020 17:25:27

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US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered '0'		12 Aug 2020 17:25:27

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'Yes (Y)'		12 Aug 2020 17:25:27

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered empty.		12 Aug 2020 17:25:27

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'No (N)'		12 Aug 2020 17:25:27

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 17:25:27

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 17:25:27

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 17:25:27

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 17:27:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 17:27:05
Data point term sent to Coder	System	12 Aug 2020 17:26:29
User entered 'Amlodipine'	(b) (4), (b) (6)	12 Aug 2020 17:26:17

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:43:55
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
User closed query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual medical condition recorded in MH eCRF. Please review and confirm prophylaxis indication if appropriate. Update or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 11:40:42
Query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual medical condition recorded in MH eCRF. Please review and confirm prophylaxis indication if appropriate. Update or provide clarification. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	24 Sep 2020 16:02:09
DataPoint Un-verified.	Dawn Killian (b) (4) (b) (4)	24 Sep 2020 16:02:04
User entered 'No (N)' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	24 Sep 2020 16:02:04
User opened query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual medical condition recorded in MH eCRF. Please review and confirm prophylaxis indication if appropriate. Update or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 10:46:19
DataPoint Verified.		27 Aug 2020 17:34:48
User entered 'Yes (Y)'		12 Aug 2020 17:26:17

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'Hypertension'		12 Aug 2020 17:26:17

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:43

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered '5'		12 Aug 2020 17:26:17

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:43

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'mg (mg)'		12 Aug 2020 17:26:17

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered empty.		12 Aug 2020 17:26:17

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:43

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'once daily (QD)'		12 Aug 2020 17:26:17

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered empty.		12 Aug 2020 17:26:17

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:43

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'Oral (ORAL)'		12 Aug 2020 17:26:17

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered empty.		12 Aug 2020 17:26:17

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		14 Aug 2020 00:37:54
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 17:31:18
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 17:26:17
User entered 'un UNK 2013'	(b) (4), (b) (6)	12 Aug 2020 17:26:17

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered '0'		12 Aug 2020 17:26:17

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'Yes (Y)'		12 Aug 2020 17:26:17

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered empty.		12 Aug 2020 17:26:17

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'No (N)'		12 Aug 2020 17:26:17

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 17:26:17

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 17:26:17

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 17:26:17

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 17:28:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 17:28:08
Data point term sent to Coder	System	12 Aug 2020 17:27:30
User entered 'Simvastatin'	(b) (4), (b) (6)	12 Aug 2020 17:27:23

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:21:43

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:44:03
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:40
User closed query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual medical condition recorded in MH eCRF. Please review and confirm prophylaxis indication if appropriate. Update or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 11:40:56
Query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual medical condition recorded in MH eCRF. Please review and confirm prophylaxis indication if appropriate. Update or provide clarification. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	24 Sep 2020 16:02:22
DataPoint Un-verified.	Dawn Killian (b) (4) (b) (4)	24 Sep 2020 16:02:18
User entered 'No (N)' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	24 Sep 2020 16:02:18
User opened query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual medical condition recorded in MH eCRF. Please review and confirm prophylaxis indication if appropriate. Updat or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 03:43:22
DataPoint Verified.		27 Aug 2020 17:34:48
User entered 'Yes (Y)'		12 Aug 2020 17:27:23

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'Hypercholesterol'		12 Aug 2020 17:27:23

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:43

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered '25'		12 Aug 2020 17:27:23

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:43

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'mg (mg)'		12 Aug 2020 17:27:23

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered empty.		12 Aug 2020 17:27:23

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:43

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'once daily (QD)'		12 Aug 2020 17:27:23

FDA-CBER-2022-1614-1667464

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered empty.		12 Aug 2020 17:27:23

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:43

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'Oral (ORAL)'		12 Aug 2020 17:27:23

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered empty.		12 Aug 2020 17:27:23

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		14 Aug 2020 00:37:58
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 17:31:03
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 17:27:23
User entered 'un UNK 2016'	(b) (4), (b) (6)	12 Aug 2020 17:27:23

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered '0'		12 Aug 2020 17:27:23

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'Yes (Y)'		12 Aug 2020 17:27:23

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered empty.		12 Aug 2020 17:27:23

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'No (N)'		12 Aug 2020 17:27:23

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 17:27:23

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 17:27:23

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 17:27:23

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE, PRODUCTSYNONYM: HCTZ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 14:05:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 14:05:20
Data point term sent to Coder	System	12 Aug 2020 17:29:34
User entered 'Hydrochlorothiazide (HCTZ)'	(b) (4), (b) (6)	12 Aug 2020 17:29:07

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:44:11
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:40
User closed query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual medical condition recorded in MH eCRF. Please review and confirm prophylaxis indication if appropriate. Update or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 11:41:09
Query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual medical condition recorded in MH eCRF. Please review and confirm prophylaxis indication if appropriate. Update or provide clarification. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	24 Sep 2020 16:02:33
DataPoint Un-verified.	Dawn Killian (b) (4) (b) (4)	24 Sep 2020 16:02:28
User entered 'No (N)' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	24 Sep 2020 16:02:28
User opened query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual medical condition recorded in MH eCRF. Please review and confirm prophylaxis indication if appropriate. Update or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 03:42:12
DataPoint Verified.		27 Aug 2020 17:34:48
User entered 'Yes (Y)'		12 Aug 2020 17:29:07

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'Hypertension'		12 Aug 2020 17:29:07

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:43

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered '25'		12 Aug 2020 17:29:07

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:43

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'mg (mg)'		12 Aug 2020 17:29:07

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered empty.		12 Aug 2020 17:29:07

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:43

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'once daily (QD)'		12 Aug 2020 17:29:07

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered empty.		12 Aug 2020 17:29:07

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:43

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'Oral (ORAL)'		12 Aug 2020 17:29:07

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered empty.		12 Aug 2020 17:29:07

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		14 Aug 2020 00:38:01
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 17:30:50
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 17:29:07
User entered 'un UNK 2013'	(b) (4), (b) (6)	12 Aug 2020 17:29:07

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US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered '0'		12 Aug 2020 17:29:07

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'Yes (Y)'		12 Aug 2020 17:29:07

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered empty.		12 Aug 2020 17:29:07

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'No (N)'		12 Aug 2020 17:29:07

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 17:29:07

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 17:29:07

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 17:29:07

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 12:07:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 12:07:25
Data point term sent to Coder	System	12 Aug 2020 17:30:36
User entered 'Potassium'	(b) (4), (b) (6)	12 Aug 2020 17:30:13

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:43

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 17:25:42
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).		29 Apr 2021 10:01:29
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 18:26:19
DataPoint Un-verified.	(b) (4), (b) (6)	27 Apr 2021 18:25:56
Signature has been broken.		27 Apr 2021 18:25:56
User entered 'Yes (Y)' reason for change: Data Entry Error		27 Apr 2021 18:25:56
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).		26 Apr 2021 16:06:41
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'No (N)'		12 Aug 2020 17:30:13

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'Supplement'		12 Aug 2020 17:30:13

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:43

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered '10'		12 Aug 2020 17:30:13

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:43

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'mg (mg)'		12 Aug 2020 17:30:13

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered empty.		12 Aug 2020 17:30:13

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:43

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'once daily (QD)'		12 Aug 2020 17:30:13

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered empty.		12 Aug 2020 17:30:13

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:43

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'Oral (ORAL)'		12 Aug 2020 17:30:13

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered empty.		12 Aug 2020 17:30:13

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		14 Aug 2020 00:38:04
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 17:30:32
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 17:30:13
User entered 'un UNK 2013'	(b) (4), (b) (6)	12 Aug 2020 17:30:13

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered '0'		12 Aug 2020 17:30:13

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'Yes (Y)'		12 Aug 2020 17:30:13

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered empty.		12 Aug 2020 17:30:13

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 17:34:48
User entered 'No (N)'		12 Aug 2020 17:30:13

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 17:30:13

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 17:30:13

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 17:30:13

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:42:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:50:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:50:59
Data point term sent to Coder	System	27 Aug 2020 18:52:34
User entered 'multivitamins'	Dawn Killian (b) (4) (b) (4)	27 Aug 2020 18:52:30

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:43

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:25:57
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 10:01:35
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 18:28:03
DataPoint Un-verified.	(b) (4), (b) (6)	27 Apr 2021 18:27:31
Signature has been broken.		27 Apr 2021 18:27:31
User entered 'Yes (Y)' reason for change: Data Entry Error		27 Apr 2021 18:27:31
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).		26 Apr 2021 16:06:52
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 20:42:36
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	27 Aug 2020 18:52:30

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 20:42:36
User entered 'supplement'	Dawn Killian (b) (4) (b) (4)	27 Aug 2020 18:52:30

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:43

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 20:42:36
User entered '1'	Dawn Killian (b) (4) (b) (4)	27 Aug 2020 18:52:30

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:43

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 20:42:36
User entered 'tablet (TABLET)'	Dawn Killian (b) (4) (b) (4)	27 Aug 2020 18:52:30

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 20:42:36
User entered empty.	Dawn Killian (b) (4)	27 Aug 2020 18:52:30

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:43

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 20:42:36
User entered 'once daily (QD)'	Dawn Killian (b) (4) (b) (4)	27 Aug 2020 18:52:30

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 20:42:36
User entered empty.	Dawn Killian (b) (4) (b) (4)	27 Aug 2020 18:52:30

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:43

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 20:42:36
User entered 'Oral (ORAL)'	Dawn Killian (b) (4) (b) (4)	27 Aug 2020 18:52:30

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 20:42:36
User entered empty.	Dawn Killian (b) (4) (b) (4)	27 Aug 2020 18:52:30

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 20:42:36
User entered 'UN UNK 2010'	Dawn Killian (b) (4)	27 Aug 2020 18:52:30
	(b) (4)	

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 20:42:36
User entered '0'	Dawn Killian (b) (4) (b) (4)	27 Aug 2020 18:52:30

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 20:42:36
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	27 Aug 2020 18:52:30

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 20:42:36
User entered empty.	Dawn Killian (b) (4) (b) (4)	27 Aug 2020 18:52:30

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:40
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 20:42:36
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	27 Aug 2020 18:52:30

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 18:52:30

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 18:52:30

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 18:52:30

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:03:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 19:16:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 19:16:10
Data point term sent to Coder	System	29 Mar 2021 19:15:54
User entered 'potassium'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:15:24

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:43

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:03:44
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:15:24

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:03:44
User entered 'supplement'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:15:24

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:43

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:03:44
User entered '10'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:15:24

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:43

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:14:39
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).		23 Apr 2021 06:06:09
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
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).	Antonio Gutierrez (b) (4)	21 Apr 2021 19:33:57
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	21 Apr 2021 19:33:47
User entered 'Other (OTHER)' reason for change: New Information	Antonio Gutierrez (b) (4)	21 Apr 2021 19:33:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:03:44
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).		05 Apr 2021 14:16:29
User entered 'mg (mg)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:15:24

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:43

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:14:40
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:09
DataPoint Un-verified.	(b) (4) Antonio Gutierrez (b) (4)	21 Apr 2021 19:33:47
User entered 'mEq' reason for change: New Information	Antonio Gutierrez (b) (4)	21 Apr 2021 19:33:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:03:44
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:15:24

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:43

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:03:44
User entered 'once daily (QD)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:15:24

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:03:44
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:15:24

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:21:43

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:03:44
User entered 'Oral (ORAL)'	Gerardo Pena (b) (4)	29 Mar 2021 19:15:24
	(b) (4)	

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:03:44
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:15:24

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:03:44
User entered 'UN UNK 2013'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:15:24

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:03:44
User entered '0'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:15:24

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:03:44
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:15:24

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:03:44
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:15:24

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:03:44
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:15:24

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 19:15:24

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 19:15:24

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Mar 2021 19:15:24

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:05:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:05:50
Data point term sent to Coder	System	21 Apr 2021 19:37:04
Coding entries removed.	Antonio Gutierrez (b) (4)	21 Apr 2021 19:36:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 00:35:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 00:35:16
Data point term sent to Coder	System	29 Mar 2021 19:16:55
User entered 'Aspirin'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:16:10

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:43

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:01
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:16:10

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:14:58
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (e.g. Cardiac Health). Update eCRF as appropriate. ' (Site from DM).		23 Apr 2021 06:05:43
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (e.g. Cardiac Health). Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	21 Apr 2021 19:36:16
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	21 Apr 2021 19:36:09
User entered 'PROPHYLAXIS FOR THE GENERAL cardiac HEALTH' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	21 Apr 2021 19:36:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:01
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (e.g. Cardiac Health). Update eCRF as appropriate. ' (Site from DM).		05 Apr 2021 14:09:31
User entered 'prophylaxis for the general health'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:16:10

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:43

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:01
User entered '81'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:16:10

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:43

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:01
User entered 'mg (mg)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:16:10

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:01
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:16:10

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:43

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:01
User entered 'once daily (QD)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:16:10

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:01
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:16:10

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:43

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:01
User entered 'Oral (ORAL)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:16:10

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:01
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:16:10

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:01
User entered 'UN UNK 2000'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:16:10

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:01
User entered '0'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:16:10

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:01
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:16:10

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:01
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:16:10

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:01
User entered 'No (N)'	Gerardo Pena (b) (4)	29 Mar 2021 19:16:10

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 19:16:10

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 19:16:10

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Mar 2021 19:16:10

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:21:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Apr 2021 20:04:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Apr 2021 20:04:55
Data point term sent to Coder	System	27 Apr 2021 18:58:18
Coding entries removed.	(b) (4), (b) (6)	27 Apr 2021 18:57:59
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 08:21:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 08:21:32
Data point term sent to Coder	System	29 Mar 2021 19:17:55
User entered 'Tramadol'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:17:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:43

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:58
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:40
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:17:38

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:58
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:28:32
User closed query 'Per CDM RQ: Please note that there is no AE of "PAIN FROM MOTOR VEHICLE ACCIDENT" recorded on the AE form?. Please reconcile CM and AE forms and add "PAIN FROM MOTOR VEHICLE ACCIDENT" to the AE form indicating the 'location/type' of Pain or, provide AE record number this indication pertains to. Please ensure the event name reconciles with the Con Med indication. Thank you.' (Site from DM).		29 Apr 2021 10:01:48
Query 'Per CDM RQ: Please note that there is no AE of "PAIN FROM MOTOR VEHICLE ACCIDENT" recorded on the AE form?. Please reconcile CM and AE forms and add "PAIN FROM MOTOR VEHICLE ACCIDENT" to the AE form indicating the 'location/type' of Pain or, provide AE record number this indication pertains to. Please ensure the event name reconciles with the Con Med indication. Thank you.' answered with 'AE ADDED' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 18:58:24
DataPoint Un-verified.	(b) (4), (b) (6)	27 Apr 2021 18:57:59
Signature has been broken.		27 Apr 2021 18:57:59
User entered 'GENERAL LOCALIZED PAIN FROM MOTOR VEHICLE ACCIDENT' reason for change: Data Entry Error		27 Apr 2021 18:57:59
User opened query 'Per CDM RQ: Please note that there is no AE of "PAIN FROM MOTOR VEHICLE ACCIDENT" recorded on the AE form?. Please reconcile CM and AE forms and add "PAIN FROM MOTOR VEHICLE ACCIDENT" to the AE form indicating the 'location/type' of Pain or, provide AE record number this indication pertains to. Please ensure the event name reconciles with the Con Med indication. Thank you.' (Site from DM).		26 Apr 2021 16:20:13

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
User closed query 'Per CDM: Response noted as " this has been updated in AE form" However please provide location of update such as log line number. thank you' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 16:08:47
Query 'Per CDM: Response noted as " this has been updated in AE form" However please provide location of update such as log line number. thank you' answered with 'generalized pain' (Site from DM).	Dawn Killian (b) (4) (b) (4)	23 Apr 2021 10:58:31
User opened query 'Per CDM: Response noted as " this has been updated in AE form" However please provide location of update such as log line number. thank you' (Site from DM).	(b) (4), (b) (6)	3 Apr 2021 06:20:12
User closed query 'Per DM CLR: Please review if corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).		3 Apr 2021 06:13:32
User closed query 'Per DM CLR: Please note, there is a medical condition if LEFT FOREARM SKIN TEAR during this time frame. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Else, clarify.' (Site from DM).		3 Apr 2021 06:12:38
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
Query 'Per DM CLR: Please note, there is a medical condition if LEFT FOREARM SKIN TEAR during this time frame. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Else, clarify.' answered with 'This medication not specifically indicated for skin tear ' (Site from DM).	Antonio Gutierrez (b) (4)	21 Apr 2021 19:45:10

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review if corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' answered with 'this has been updated in AE form' (Site from DM).	Antonio Gutierrez (b) (4)	21 Apr 2021 19:39:22
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:40
User opened query 'Per DM CLR: Please review if corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).		06 Apr 2021 07:32:32
User opened query 'Per DM CLR: Please note, there is a medical condition if LEFT FOREARM SKIN TEAR during this time frame. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Else, clarify.' (Site from DM).		06 Apr 2021 07:25:57
User entered 'pain from motor vehicle accident'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:17:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:43

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:58
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:40
User entered '50'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:17:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:43

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:58
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:40
User entered 'mg (mg)'	Gerardo Pena (b) (4)	29 Mar 2021 19:17:38
	(b) (4)	

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:58
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:40
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:17:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:43

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:58
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:40
User entered 'as needed (PRN)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:17:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:58
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:40
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:17:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:43

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:58
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:40
User entered 'Oral (ORAL)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:17:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:58
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:40
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:17:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:58
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:40
User entered '30 Nov 2020'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:17:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:58
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:40
User entered '0'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:17:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:58
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:40
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:17:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:58
User closed query 'Per source, end date is 04Jan2020. Pleas review and reconcile. ' (Site from CRA).		22 Apr 2021 15:59:29
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
Query 'Per source, end date is 04Jan2020. Pleas review and reconcile. ' answered with 'source updated ' (Site from CRA).	Antonio Gutierrez (b) (4)	21 Apr 2021 19:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:40
User opened query 'Per source, end date is 04Jan2020. Pleas review and reconcile. ' (Site from CRA).		20 Apr 2021 16:04:32
User entered '4 Jan 2021'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:17:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:58
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:40
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:17:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:58
User entered empty.	System	29 Mar 2021 19:17:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:58
User entered empty.	System	29 Mar 2021 19:17:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:58
User entered empty.	System	29 Mar 2021 19:17:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:59
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:31:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:31:23
Data point term sent to Coder	System	29 Mar 2021 19:20:01
User entered 'Hydromorphone'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:19:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:43

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:59
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:06
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:19:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:59
User closed query 'Per CDM: Response noted as " this was updated" However please provide location of update such as log line number. thank you' (Site from DM).		26 Apr 2021 16:09:28
Query 'Per CDM: Response noted as " this was updated" However please provide location of update such as log line number. thank you' answered with 'generalized pain' (Site from DM).	Dawn Killian (b) (4) (b) (4)	23 Apr 2021 10:58:19
User opened query 'Per CDM: Response noted as " this was updated" However please provide location of update such as log line number. thank you' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 06:19:24
User closed query 'Per DM CLR: Please review if corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).		23 Apr 2021 06:19:24
User closed query 'Per DM CLR: Please note, there is a medical condition if LEFT FOREARM SKIN TEAR during this time frame. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Else, clarify.' (Site from DM).		23 Apr 2021 06:16:49
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
Query 'Per DM CLR: Please note, there is a medical condition if LEFT FOREARM SKIN TEAR during this time frame. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Else, clarify.' answered with 'This medication not specifically indicated for skin tear ' (Site from DM).	Antonio Gutierrez (b) (4)	21 Apr 2021 19:45:49

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review if corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' answered with 'this was updated ' (Site from DM). DataPoint Verified.	Antonio Gutierrez (b) (4)	21 Apr 2021 19:45:24
	(b) (4), (b) (6)	20 Apr 2021 16:05:06
User opened query 'Per DM CLR: Please review if corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).		06 Apr 2021 07:33:08
User opened query 'Per DM CLR: Please note, there is a medical condition if LEFT FOREARM SKIN TEAR during this time frame. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Else, clarify.' (Site from DM).		06 Apr 2021 07:32:57
User entered 'pain from motor vehicle accident'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:19:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:43

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:59
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:06
User entered '0.2'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:19:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:43

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:59
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:06
User entered 'mg (mg)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:19:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:59
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:06
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:19:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:43

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:59
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:06
User entered 'as needed (PRN)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:19:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:59
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:06
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:19:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:43

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:59
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:06
User entered 'Intravenous (INTRAVENOUS)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:19:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:59
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:06
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:19:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:59
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:06
User entered '27 Nov 2020'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:19:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:59
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:06
User entered '0'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:19:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:59
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:06
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:19:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:59
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:06
User entered '27 Nov 2020'	Gerardo Pena (b) (4)	29 Mar 2021 19:19:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:59
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:06
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:19:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:59
User entered empty.	System	29 Mar 2021 19:19:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:59
User entered empty.	System	29 Mar 2021 19:19:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:59
User entered empty.	System	29 Mar 2021 19:19:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:04
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:18:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:18:21
Data point term sent to Coder	System	29 Mar 2021 19:20:01
User entered 'Gabapentin'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:20:00

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:43

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:04
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:20
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:20:00

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:04
User closed query 'Per CDM: Response noted as " this was updated" However please provide location o update such as log line number. thank you' (Site from DM).		26 Apr 2021 16:09:35
Query 'Per CDM: Response noted as " this was updated" However please provide location of update such as log line number. thank you' answered with 'generalized pain' (Site from DM).	Dawn Killian (b) (4) (b) (4)	23 Apr 2021 10:58:49
User opened query 'Per CDM: Response noted as " this was updated" However please provide location of update such as log line number. thank you' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 06:22:25
User closed query 'Per DM CLR: Please review if corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).		23 Apr 2021 06:22:25
User closed query 'Per DM CLR: Please note, there is a medical condition if LEFT FOREARM SKIN TEAR during this time frame. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Else, clarify.' (Site from DM).		23 Apr 2021 06:22:08
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
Query 'Per DM CLR: Please note, there is a medical condition if LEFT FOREARM SKIN TEAR during this time frame. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Else, clarify.' answered with 'this medication not specifically indicated for skin tear ' (Site from DM).	Antonio Gutierrez (b) (4)	21 Apr 2021 19:46:22

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Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review if corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' answered with 'this was updated ' (Site from DM). DataPoint Verified.	Antonio Gutierrez (b) (4)	21 Apr 2021 19:46:06
	(b) (4), (b) (6)	20 Apr 2021 16:05:20
User opened query 'Per DM CLR: Please review if corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).		06 Apr 2021 07:35:19
User opened query 'Per DM CLR: Please note, there is a medical condition if LEFT FOREARM SKIN TEAR during this time frame. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 07:34:56
User entered 'pain from motor vehicle accident'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:20:00

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:43

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:04
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:20
User entered '300'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:20:00

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:43

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:04
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:20
User entered 'mg (mg)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:20:00

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:04
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:20
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:20:00

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:43

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:04
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:20
User entered 'as needed (PRN)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:20:00

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:04
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:20
User entered empty.	Gerardo Pena (b) (4)	29 Mar 2021 19:20:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:43

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:04
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:20
User entered 'Oral (ORAL)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:20:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:04
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:20
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:20:00

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:04
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:20
User entered '17 Dec 2020'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:20:00

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:04
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:20
User entered '0'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:20:00

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:04
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:20
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:20:00

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:04
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:20
User entered '11 Jan 2021'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:20:00

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:04
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:05:20
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:20:00

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:04
User entered empty.	System	29 Mar 2021 19:20:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:04
User entered empty.	System	29 Mar 2021 19:20:00

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:04
User entered empty.	System	29 Mar 2021 19:20:00

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:07
User closed query 'Per DM CLR: Please note this medication is not expected to be given for this medical condition. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure AE eCRF is updated to reflect this update. ' (Site from DM).		23 Apr 2021 06:25:31
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: SENNA ALEXANDRINA GLYCOSIDE EXTRACT, PRODUCTSYNONYM: SENNA GLYCOSIDES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 07:39:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 07:39:13
Data point term sent to Coder	System	21 Apr 2021 19:50:17
Query 'Per DM CLR: Please note this medication is not expected to be given for this medical condition. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure AE eCRF is updated to reflect this update. ' answered with 'updated ' (Site from DM).	Antonio Gutierrez (b) (4)	21 Apr 2021 19:50:13
Coding entries removed.	Antonio Gutierrez (b) (4)	21 Apr 2021 19:50:07
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:00
User opened query 'Per DM CLR: Please note this medication is not expected to be given for this medical condition. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure AE eCRF is updated to reflect this update. ' (Site from DM).		06 Apr 2021 07:35:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:43

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: SENNA ALEXANDRINA GLYCOSIDE EXTRACT, PRODUCTSYNONYM: SENNA GLYCOSIDES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 08:40:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 08:40:57
Data point term sent to Coder	System	29 Mar 2021 19:27:14
User entered 'Senna glycoside'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:26:59

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:43

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:07
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:00
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:26:59

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:07
DataPoint Verified.		22 Apr 2021 20:41:57
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	21 Apr 2021 19:50:07
User entered 'INTERNAL GI HEMORRHAGE - MOTOR VEHICAL ACCIDENT' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	21 Apr 2021 19:50:07
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:00
User entered 'motor vehicle accident'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:26:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:43

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:07
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:00
User entered '17.2'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:26:59

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:43

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:07
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:00
User entered 'mg (mg)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:26:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:07
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:00
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:26:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:43

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:07
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:00
User entered 'other (OTHER)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:26:59

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:07
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:00
User entered 'Every night at bedtime'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:26:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:43

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:07
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:00
User entered 'Oral (ORAL)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:26:59

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:07
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:00
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:26:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:07
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:00
User entered '17 Dec 2020'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:26:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:07
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:00
User entered '0'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:26:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:07
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:00
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:26:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:07
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:00
User entered '11 Jan 2021'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:26:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:07
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:00
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:26:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:07
User entered empty.	System	29 Mar 2021 19:26:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:07
User entered empty.	System	29 Mar 2021 19:26:59

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:07
User entered empty.	System	29 Mar 2021 19:26:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:11
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: SOLUTIONS FOR PARENTERAL NUTRITION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 07:23:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 07:23:47
Data point term sent to Coder	System	21 Apr 2021 19:49:16
Coding entries removed.	Antonio Gutierrez (b) (4)	21 Apr 2021 19:48:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:19
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: POTASSIUM PHOSPHATE DIBASIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 11:11:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 11:11:31
Data point term sent to Coder	System	29 Mar 2021 19:29:16
User entered 'potassium phosphate in normal saline'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:28:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:43

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:11
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:19
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:28:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:11
User closed query 'Per DM CLR: Please note, there is a medical condition if INTERNAL HEMORRHAGE - MOTOR VEHICAL ACCIDENT during this time frame. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match.' (Site from DM).		23 Apr 2021 06:24:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:42:02
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:09
Query 'Per DM CLR: Please note, there is a medical condition if INTERNAL HEMORRHAGE - MOTOR VEHICAL ACCIDENT during this time frame. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match.' answered with 'updated ' (Site from DM).	(b) (4) Antonio Gutierrez (b) (4)	21 Apr 2021 19:48:59
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	21 Apr 2021 19:48:38
User entered 'INTERNAL GI HEMORRHAGE - MOTOR VEHICAL ACCIDENT' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	21 Apr 2021 19:48:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:19
User opened query 'Per DM CLR: Please note, there is a medical condition if INTERNAL HEMORRHAGE - MOTOR VEHICAL ACCIDENT during this time frame. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match.' (Site from DM).		06 Apr 2021 07:39:10
User entered 'motor vehicle accident'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:28:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:43

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:11
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:19
User entered '15'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:28:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:43

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:11
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:19
User entered 'Other (OTHER)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:28:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:11
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:19
User entered 'Mmol'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:28:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:43

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:11
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:19
User entered 'other (OTHER)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:28:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:11
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:19
User entered 'every three hours'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:28:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:43

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:11
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:19
User entered 'Intravenous (INTRAVENOUS)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:28:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:11
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:19
User entered empty.	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:28:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:11
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:19
User entered '17 Dec 2020'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:28:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:11
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:19
User entered '0'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:28:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:11
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:19
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:28:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:11
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:19
User entered '11 Jan 2021'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:28:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:11
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:06:19
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	29 Mar 2021 19:28:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:11
User entered empty.	System	29 Mar 2021 19:28:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:11
User entered empty.	System	29 Mar 2021 19:28:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:11
User entered empty.	System	29 Mar 2021 19:28:38

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:13
DataPoint Verified.		23 Apr 2021 19:16:26
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:32:39
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b)(4) (b) (4)	23 Apr 2021 02:46:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 02:46:40
Data point term sent to Coder	System	22 Apr 2021 21:09:24
User entered 'simvastatin'	(b) (4), (b) (6)	22 Apr 2021 21:09:05

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:43

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:13
DataPoint Verified.		23 Apr 2021 19:16:26
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:09:05

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:16:26
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Motor Vehicle Accident'	(b) (4), (b) (6)	22 Apr 2021 21:09:05

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:43

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:16:26
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '20'	(b) (4), (b) (6)	22 Apr 2021 21:09:05

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:16:26
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:09:05

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:13
DataPoint Verified.		23 Apr 2021 19:16:26
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:09:05

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:43

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:13
DataPoint Verified.		23 Apr 2021 19:16:26
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:09:05

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:16:26
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'QHS'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:09:05

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:43

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:13
DataPoint Verified.		23 Apr 2021 19:16:26
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:09:05

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:13
DataPoint Verified.		23 Apr 2021 19:16:26
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:09:05

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:13
DataPoint Verified.		23 Apr 2021 19:16:26
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '17 Dec 2020'	(b) (4), (b) (6)	22 Apr 2021 21:09:05

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 16:21:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:16:26
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:09:05

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:13
DataPoint Verified.		23 Apr 2021 19:16:26
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:09:05

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:16:26
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:09:05

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:13
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:16:26
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:09:05

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:13
User entered empty.	System	22 Apr 2021 21:09:05

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:13
User entered empty.	System	22 Apr 2021 21:09:05

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:13
User entered empty.	System	22 Apr 2021 21:09:05

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:17
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:16:45
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:32:39
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 02:00:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 02:00:41
Data point term sent to Coder	System	22 Apr 2021 21:11:26
User entered 'Decadron'	(b) (4), (b) (6)	22 Apr 2021 21:10:58

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:43

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:17
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:16:45
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:10:58

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:17
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:16:45
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Motor Vehicle Accident'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:10:58

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:43

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:17
DataPoint Verified.		23 Apr 2021 19:16:45
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:32:39
User entered '10'	(b) (4), (b) (6)	22 Apr 2021 21:10:58

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:21:43

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:17
DataPoint Verified.		23 Apr 2021 19:16:45
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:10:58

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:17
DataPoint Verified.		23 Apr 2021 19:16:45
User signature succeeded.	(b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4), (b) (4), (b) (6)	22 Apr 2021 21:10:58

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:43

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:17
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:16:45
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:10:58

US3292127
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 16:21:43
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:17
DataPoint Verified.		23 Apr 2021 19:16:45
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:10:58

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:43

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:17
DataPoint Verified.		23 Apr 2021 19:16:45
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	22 Apr 2021 21:10:58

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:17
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:16:45
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:10:58

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:17
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:16:45
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '17 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:10:58

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:17
DataPoint Verified.		23 Apr 2021 19:16:45
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:10:58

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:17
DataPoint Verified.		23 Apr 2021 19:16:45
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:10:58

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:17
DataPoint Verified.		23 Apr 2021 19:16:45
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:10:58

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:17
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:16:45
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:10:58

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:17
User entered '3'	System	22 Apr 2021 21:10:58

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:17
User entered '1'	System	22 Apr 2021 21:10:58

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:17
User entered '804 (804)'	System	22 Apr 2021 21:10:58

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:21
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:19:02
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:32:39
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL, PRODUCTSYNONYM: OMNIPAQUE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 02:40:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 02:40:42
Data point term sent to Coder	System	22 Apr 2021 21:12:27
User entered 'Omnipaque 350 mg/mL'	(b) (4), (b) (6)	22 Apr 2021 21:12:21

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:43

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:21
DataPoint Verified.		23 Apr 2021 19:19:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:12:21

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:21
DataPoint Verified.		23 Apr 2021 19:19:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Motor Vehicle Accident'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:12:21

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:43

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:21
DataPoint Verified.		23 Apr 2021 19:19:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '100'	(b) (4), (b) (6)	22 Apr 2021 21:12:21

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:43

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:21
DataPoint Verified.		23 Apr 2021 19:19:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'mL (mL)'	(b) (4), (b) (6)	22 Apr 2021 21:12:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:21
DataPoint Verified.		23 Apr 2021 19:19:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:12:21

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:43

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:21
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:19:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'once (ONCE)'	(b) (4), (b) (6)	22 Apr 2021 21:12:21

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:21
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:19:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:12:21

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:43

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:21
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:19:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	22 Apr 2021 21:12:21

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:21
DataPoint Verified.		23 Apr 2021 19:19:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 21:12:21

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:21
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:19:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '17 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:12:21

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:21
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:19:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:12:21

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:21
DataPoint Verified.		23 Apr 2021 19:19:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:12:21

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:21
DataPoint Verified.		23 Apr 2021 19:19:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '17 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:12:21

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:21
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:19:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:12:21

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:21
User entered empty.	System	22 Apr 2021 21:12:21

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:21
User entered empty.	System	22 Apr 2021 21:12:21

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:21
User entered empty.	System	22 Apr 2021 21:12:21

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 16:21:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:24
DataPoint Verified.		23 Apr 2021 19:19:24
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:32:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 02:04:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 02:04:45
Data point term sent to Coder	System	22 Apr 2021 21:14:29
User entered 'Docusate Sodium'	(b) (4), (b) (6)	22 Apr 2021 21:13:36

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:43

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:24
DataPoint Verified.		23 Apr 2021 19:19:24
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'No (N)'	(b) (4), (b) (6)	22 Apr 2021 21:13:36

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:24
DataPoint Verified.		23 Apr 2021 19:19:24
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Motor Vehicle Accident'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:13:36

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:43

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:24
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:19:24
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '100'	(b) (4), (b) (6)	22 Apr 2021 21:13:36

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:43

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:24
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:19:24
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:13:36

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:24
DataPoint Verified.		23 Apr 2021 19:19:24
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 21:13:36

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:43

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:24
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:19:24
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:13:36

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:24
DataPoint Verified.		23 Apr 2021 19:19:24
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:13:36

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:43

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:24
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:19:24
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:13:36

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:24
DataPoint Verified.		23 Apr 2021 19:19:24
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 21:13:36

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:24
DataPoint Verified.		23 Apr 2021 19:19:24
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '30 Nov 2020'	(b) (4), (b) (6)	22 Apr 2021 21:13:36

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:24
DataPoint Verified.		23 Apr 2021 19:19:24
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 21:13:36

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:24
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:19:24
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:13:36

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:24
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:19:24
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '4 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:13:36

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:24
DataPoint Verified.		23 Apr 2021 19:19:24
User signature succeeded.	(b) (4)	23 Apr 2021 18:32:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:13:36

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:24
User entered '2'	System	22 Apr 2021 21:13:36

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:24
User entered '1'	System	22 Apr 2021 21:13:36

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:24
User entered '804 (804)'	System	22 Apr 2021 21:13:36

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:29
DataPoint Verified.		23 Apr 2021 19:19:49
User signature succeeded.	(b) (4)	23 Apr 2021 18:32:39
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 02:04:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 02:04:45
Data point term sent to Coder	System	22 Apr 2021 21:16:31
User entered 'Enoxaparin'	(b) (4), (b) (6)	22 Apr 2021 21:15:45

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:43

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:29
DataPoint Verified.		23 Apr 2021 19:19:49
User signature succeeded.	(b) (4)	23 Apr 2021 18:32:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:15:45

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:29
DataPoint Verified.		23 Apr 2021 19:19:49
User signature succeeded.	(b) (4)	23 Apr 2021 18:32:39
User entered 'Motor Vehicle Accident'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:15:45

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:43

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:29
DataPoint Verified.		23 Apr 2021 19:19:49
User signature succeeded.	(b) (4)	23 Apr 2021 18:32:39
User entered '30'	(b) (4), (b) (6)	22 Apr 2021 21:15:45

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:43

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:29
DataPoint Verified.		23 Apr 2021 19:19:49
User signature succeeded.	(b) (4)	23 Apr 2021 18:32:39
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:15:45

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:29
DataPoint Verified.		23 Apr 2021 19:19:49
User signature succeeded.	(b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 21:15:45

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:43

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:29
DataPoint Verified.		23 Apr 2021 19:19:49
User signature succeeded.	(b) (4)	23 Apr 2021 18:32:39
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:15:45

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:29
DataPoint Verified.		23 Apr 2021 19:19:49
User signature succeeded.	(b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) / (b) (4), (b) (6)	22 Apr 2021 21:15:45

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:43

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:29
DataPoint Verified.		23 Apr 2021 19:19:49
User signature succeeded.	(b) (4)	23 Apr 2021 18:32:39
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	22 Apr 2021 21:15:45

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:29
DataPoint Verified.		23 Apr 2021 19:19:49
User signature succeeded.	(b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:15:45

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:29
DataPoint Verified.		23 Apr 2021 19:19:49
User signature succeeded.	(b) (4)	23 Apr 2021 18:32:39
User entered '30 Nov 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:15:45

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:29
DataPoint Verified.		23 Apr 2021 19:19:49
User signature succeeded.	(b) (4)	23 Apr 2021 18:32:39
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:15:45

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:29
DataPoint Verified.		23 Apr 2021 19:19:49
User signature succeeded.	(b) (4)	23 Apr 2021 18:32:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:15:45

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:29
DataPoint Verified.		23 Apr 2021 19:19:49
User signature succeeded.	(b) (4)	23 Apr 2021 18:32:39
User entered '4 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:15:45

US3292127

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 16:21:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:29
DataPoint Verified.		23 Apr 2021 19:19:49
User signature succeeded.	(b) (4)	23 Apr 2021 18:32:39
User entered 'No (N)'	(b) (4), (b) (6)	22 Apr 2021 21:15:45

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:29
User entered '2'	System	22 Apr 2021 21:15:45

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:29
User entered '1'	System	22 Apr 2021 21:15:45

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:29
User entered '804 (804)'	System	22 Apr 2021 21:15:45

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:31
DataPoint Verified.		23 Apr 2021 19:20:06
User signature succeeded.	(b) (4) (b) (4)	23 Apr 2021 18:32:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 02:23:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 02:23:50
Data point term sent to Coder	System	22 Apr 2021 21:17:32
User entered 'Morphine Sulfate'	(b) (4), (b) (6)	22 Apr 2021 21:17:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:43

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:31
DataPoint Verified.		23 Apr 2021 19:20:06
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'No (N)'	(b) (4), (b) (6)	22 Apr 2021 21:17:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:31
DataPoint Verified.		23 Apr 2021 19:20:06
User signature succeeded.	(b) (4)	23 Apr 2021 18:32:39
User entered 'Motor Vehicle Accident'	(b) (4), (b) (6)	22 Apr 2021 21:17:06

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:31
DataPoint Verified.		23 Apr 2021 19:20:06
User signature succeeded.	(b) (4)	23 Apr 2021 18:32:39
User entered '2'	(b) (4)	22 Apr 2021 21:17:06
	(b) (4), (b) (6)	

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:43

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:31
DataPoint Verified.		23 Apr 2021 19:20:06
User signature succeeded.	(b) (4)	23 Apr 2021 18:32:39
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:17:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:31
DataPoint Verified.		23 Apr 2021 19:20:06
User signature succeeded.	(b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:17:06

US3292127

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 16:21:43

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:31
DataPoint Verified.		23 Apr 2021 19:20:06
User signature succeeded.	(b) (4)	23 Apr 2021 18:32:39
User entered 'as needed (PRN)'	(b) (4) / (b) (4), (b) (6)	22 Apr 2021 21:17:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:31
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:20:06
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:17:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:43

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:31
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:20:06
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:17:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:31
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:20:06
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 21:17:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:31
DataPoint Verified.		23 Apr 2021 19:20:06
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '26 Nov 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:17:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:31
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:20:06
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:17:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:31
DataPoint Verified.		23 Apr 2021 19:20:06
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'No (N)'	(b) (4), (b) (6)	22 Apr 2021 21:17:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:31
DataPoint Verified.		23 Apr 2021 19:20:06
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '4 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:17:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:31
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:20:06
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'No (N)'	(b) (4), (b) (6)	22 Apr 2021 21:17:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:31
User entered empty.	System	22 Apr 2021 21:17:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:31
User entered empty.	System	22 Apr 2021 21:17:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:31
User entered empty.	System	22 Apr 2021 21:17:06

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:20:23
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:32:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 02:40:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 02:40:42
Data point term sent to Coder	System	22 Apr 2021 21:18:32
User entered 'Ondansetron'	(b) (4), (b) (6)	22 Apr 2021 21:18:26

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:43

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:20:23
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:18:26

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:20:23
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Motor Vehicle Accident'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:18:26

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:43

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:20:23
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '4'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:18:26

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:43

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:20:23
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:18:26

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:20:23
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 21:18:26

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:43

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:20:23
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'as needed (PRN)'	(b) (4), (b) (6)	22 Apr 2021 21:18:26

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:33
DataPoint Verified.		23 Apr 2021 19:20:23
User signature succeeded.	(b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:18:26

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:43

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:20:23
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:18:26

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:20:23
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:18:26

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:43

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:20:23
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '25 Nov 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:18:26

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:20:23
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:18:26

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:43

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:20:23
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:18:26

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:20:23
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '4 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:18:26

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:20:23
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:18:26

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:33
User entered empty.	System	22 Apr 2021 21:18:26

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:33
User entered empty.	System	22 Apr 2021 21:18:26

US3292127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:21:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:33
User entered empty.	System	22 Apr 2021 21:18:26

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:21:43

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:48:57
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	03 Mar 2021 14:12:23
Signature has been broken.	(b) (4), (b) (6)	27 Feb 2021 17:06:49
User entered 'Yes (Y)' reason for change: Data Entry Error		27 Feb 2021 17:06:49
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:40
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	04 Feb 2021 16:22:36

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:49:26
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered '25 Nov 2020'	(b) (4), (b) (6)	27 Feb 2021 17:08:13

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:02:18
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:03:06
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	13 Apr 2021 19:39:00
Signature has been broken.	Antonio Gutierrez (b) (4)	13 Apr 2021 19:39:00
User entered 'FOUR COMPARTMENT FASCIOTOMY (RLE)' reason for change: New Information	Antonio Gutierrez (b) (4)	13 Apr 2021 19:39:00
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:49:26
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	03 Mar 2021 14:12:23
User entered 'four compartment fasciotomy'	(b) (4), (b) (6)	27 Feb 2021 17:08:13

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:49:26
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	(b) (4) System	27 Feb 2021 17:08:31
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	27 Feb 2021 17:08:13
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	27 Feb 2021 17:08:13

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:21:43

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:49:26
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	27 Feb 2021 17:08:31
User entered 'right calf hematoma'		27 Feb 2021 17:08:13

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:02:38
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:06
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	13 Apr 2021 19:39:59
Signature has been broken.	Antonio Gutierrez (b) (4)	13 Apr 2021 19:39:59
User entered '28 Nov 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	13 Apr 2021 19:39:59
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:49:26
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered '25 Nov 2020'	(b) (4), (b) (6)	27 Feb 2021 17:09:11

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:02:33
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:03:06
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	13 Apr 2021 19:39:59
Signature has been broken.	Antonio Gutierrez (b) (4)	13 Apr 2021 19:39:59
User entered 'Debridement RLE Wound VAC placement' reason for change: New Information	Antonio Gutierrez (b) (4)	13 Apr 2021 19:39:59
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:49:26
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	03 Mar 2021 14:12:23
User entered 'wound debridement'	(b) (4), (b) (6)	27 Feb 2021 17:09:11

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:49:26
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	27 Feb 2021 17:09:11

US3292127
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 09 Jun 2021 16:21:43
If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:49:26
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered empty.	(b) (4), (b) (6)	27 Feb 2021 17:09:11

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:02:45
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:06
DataPoint Un-verified.	(b) (4) Antonio Gutierrez (b) (4)	13 Apr 2021 19:43:16
Signature has been broken.	Antonio Gutierrez (b) (4)	13 Apr 2021 19:43:16
User entered '01 Dec 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	13 Apr 2021 19:43:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:49:26
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered '25 Nov 2020'	(b) (4) (b) (4), (b) (6)	27 Feb 2021 17:09:49

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:02:52
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:06
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	13 Apr 2021 19:43:16
Signature has been broken.	Antonio Gutierrez (b) (4)	13 Apr 2021 19:43:16
User entered 'Excisional debridement RLE wound vac placement' reason for change: New Information	Antonio Gutierrez (b) (4)	13 Apr 2021 19:43:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:49:26
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered 'wound vac placement'	(b) (4), (b) (6)	27 Feb 2021 17:09:49

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:49:26
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	27 Feb 2021 17:09:49

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:21:43

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:49:26
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered empty.	(b) (4), (b) (6)	27 Feb 2021 17:09:49

US3292127
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 09 Jun 2021 16:21:43
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:49:26
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered '25 Nov 2020'	(b) (4), (b) (6)	27 Feb 2021 17:11:31

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:49:26
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered 'ct abdominal pelvis'	(b) (4), (b) (6)	27 Feb 2021 17:11:31

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:49:26
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	27 Feb 2021 17:11:31

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:21:43

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:49:26
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:12:23
User entered empty.	(b) (4), (b) (6)	27 Feb 2021 17:11:31

Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 09 Jun 2021 16:21:43
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:19:41

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Debridement of Wound'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:19:41

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:19:41

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:21:43

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:19:41

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:46
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '19 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:20:07

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:46
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'EGD'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:20:07

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:46
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	22 Apr 2021 21:20:07

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:21:43

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:46
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 21:20:07

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:53
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '20 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:20:38

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:53
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Blood Transfusion'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:20:38

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:53
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:20:38

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:21:43

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:53
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:20:38

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:56
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '22 Dec 2020'	(b) (4), (b) (6)	22 Apr 2021 21:31:00

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:56
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Blood Transfusion'	(b) (4), (b) (6)	22 Apr 2021 21:31:00

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:56
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:31:00

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:21:43

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:56
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:31:00

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:32
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '21 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:31:42

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:32
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'EGD'	(b) (4), (b) (6)	22 Apr 2021 21:31:42

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:32
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	22 Apr 2021 21:31:42

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 16:21:43

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:32
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 21:31:42

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '23 Dec 2020'	(b) (4), (b) (6)	22 Apr 2021 21:32:26

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:36
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:32:39
User entered 'Blood Transfusion'	(b) (4), (b) (6)	22 Apr 2021 21:32:26

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	22 Apr 2021 21:32:26

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 16:21:43

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 21:32:26

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '25 Dec 2020'	(b) (4), (b) (6)	22 Apr 2021 21:32:57

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Blood Transfusion'	(b) (4), (b) (6)	22 Apr 2021 21:32:57

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:32:57

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 16:21:43

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:32:57

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:41
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '27 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:33:28

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:41
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Blood Transfusion'	(b) (4), (b) (6)	22 Apr 2021 21:33:28

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:41
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	22 Apr 2021 21:33:28

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 16:21:43

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:41
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:33:28

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:11
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '28 Dec 2020'	(b) (4), (b) (6)	22 Apr 2021 21:34:11

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:11
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Blood Transfusion'	(b) (4), (b) (6)	22 Apr 2021 21:34:11

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:11
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	22 Apr 2021 21:34:11

US3292127
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (13)
Generated On: 09 Jun 2021 16:21:43
If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:11
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 21:34:11

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:13
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '21 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:34:35

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:13
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Hemostatic Clips'	(b) (4), (b) (6)	22 Apr 2021 21:34:35

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:13
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:34:35

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 16:21:43

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:13
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:34:35

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:18
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '21 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:34:59

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:18
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Colonoscopy'	(b) (4), (b) (6)	22 Apr 2021 21:34:59

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:18
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	22 Apr 2021 21:34:59

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 09 Jun 2021 16:21:43

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:18
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:34:59

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:24
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '28 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:35:25

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:24
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'EGD'	(b) (4), (b) (6)	22 Apr 2021 21:35:25

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:24
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:35:25

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 09 Jun 2021 16:21:43

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:24:24
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 21:35:25

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:46
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '28 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:36:11

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:46
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Hemostatic Clips'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:36:11

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:46
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	22 Apr 2021 21:36:11

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 09 Jun 2021 16:21:43

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:46
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:36:11

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:53
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '17 Dec 2020'	(b) (4), (b) (6)	22 Apr 2021 21:36:39

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:53
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Doppler Ultrasound'	(b) (4), (b) (6)	22 Apr 2021 21:36:39

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:53
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:36:39

US3292127
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (18)
Generated On: 09 Jun 2021 16:21:43
If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:53
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:36:39

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:55
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '1 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:37:10

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:55
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Doppler Ultrasound'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:37:10

US3292127
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (19)
Generated On: 09 Jun 2021 16:21:43
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:55
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:37:10

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 09 Jun 2021 16:21:43

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:55
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:37:10

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:58
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '17 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:37:35

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:58
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Chest X-Ray'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:37:35

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:58
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:37:35

US3292127
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (20)
Generated On: 09 Jun 2021 16:21:43
If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:58
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:37:35

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:25
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '28 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:38:04

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:25
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Chest X-Ray'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:38:04

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:25
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:38:04

US3292127
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (21)
Generated On: 09 Jun 2021 16:21:43
If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:25
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:38:04

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:27
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '29 Dec 2020'	(b) (4), (b) (6)	22 Apr 2021 21:38:37

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:27
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Chest X-Ray'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:38:37

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:27
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	22 Apr 2021 21:38:37

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 09 Jun 2021 16:21:43

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:27
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:38:37

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:30
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '30 Dec 2020'	(b) (4), (b) (6)	22 Apr 2021 21:39:01

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:30
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Chest X-Ray'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:39:01

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:30
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:39:01

US3292127
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (23)
Generated On: 09 Jun 2021 16:21:43
If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:30
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:39:01

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '29 Dec 2020'	(b) (4), (b) (6)	22 Apr 2021 21:39:28

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Embolization'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:39:28

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:39:28

US3292127
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (24)
Generated On: 09 Jun 2021 16:21:43
If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:39:28

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (25)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:14
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered '29 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:39:59

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (25)

Generated On: 09 Jun 2021 16:21:43

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:14
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'CT-Abdomen'	(b) (4), (b) (6)	22 Apr 2021 21:39:59

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (25)

Generated On: 09 Jun 2021 16:21:43

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:14
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	22 Apr 2021 21:39:59

US3292127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (25)

Generated On: 09 Jun 2021 16:21:43

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:23:14
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 21:39:59

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'USA-US072-2020-MRNA-1273-P301000015'	System	03 Dec 2020 16:54:54

PRODUCTION RELEASE (v12.003 EAB) (1725)

Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Yes (Y)'	System	03 Dec 2020 16:54:54

Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

FDA-CBER-2022-1614-1667890

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:43

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		3 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Yes (Y)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

FDA-CBER-2022-1614-1667893

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

FDA-CBER-2022-1614-1667894

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Douglas'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Denham'		03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered '7940 Floyd Curl Drive'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'San Antonio'		03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered '78229'	System	03 Dec 2020 16:54:54

FDA-CBER-2022-1614-1667900

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		11 Dec 2020 15:54:44
User entered 'US'	System	03 Dec 2020 16:56:04

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 13:20:22
User entered '9'	System	23 Apr 2021 15:00:45
User entered '8'	System	22 Apr 2021 13:56:24
User entered '7'	System	20 Apr 2021 14:41:28
User entered '6'	System	14 Apr 2021 14:50:11
User entered '5'	System	12 Apr 2021 16:31:12
User entered '4'	System	01 Mar 2021 20:55:44
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '3'	System	22 Feb 2021 15:07:37
User entered '2'	System	11 Dec 2020 15:58:54
User entered '1'	System	03 Dec 2020 16:56:04

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43

SAEID

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'USA-US072-2020-MRNA-1273-P301000015'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Yes (Y)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'		03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'		03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Yes (Y)'	System	03 Dec 2020 16:54:54

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'		03 Dec 2020 16:54:54

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

FDA-CBER-2022-1614-1667909

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'		03 Dec 2020 16:54:54

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Douglas'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Denham'	System	03 Dec 2020 16:54:54

PRODUCTION RELEASE (v12.003
EAB) (1725)

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered '7940 Floyd Curl Drive'		03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'San Antonio'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered '78229'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		11 Dec 2020 15:54:44
User entered 'US'		03 Dec 2020 16:56:04

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 13:20:22
User entered '9'	System	23 Apr 2021 15:00:45
User entered '8'	System	22 Apr 2021 13:56:24
User entered '7'	System	20 Apr 2021 14:41:28
User entered '6'	System	14 Apr 2021 14:50:11
User entered '5'	System	12 Apr 2021 16:31:12
User entered '4'	System	01 Mar 2021 20:55:44
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '3'	System	22 Feb 2021 15:07:37
User entered '2'	System	11 Dec 2020 15:58:54
User entered '1'	System	03 Dec 2020 16:56:04

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form (1)
Generated On: 09 Jun 2021 16:21:43
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
User entered '03/Dec/2020 16:56'	System	03 Dec 2020 16:56:04

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:21:43

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.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		11 Dec 2020 15:54:44
User entered '1'		03 Dec 2020 16:56:04

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'USA-US072-2020-MRNA-1273-P301000015'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Yes (Y)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Yes (Y)'	System	03 Dec 2020 16:54:54

FDA-CBER-2022-1614-1667924

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'		03 Dec 2020 16:54:54

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Douglas'	System	03 Dec 2020 16:54:54

FDA-CBER-2022-1614-1667928

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Denham'	System	03 Dec 2020 16:54:54

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered '7940 Floyd Curl Drive'	System	03 Dec 2020 16:54:54

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'San Antonio'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered '78229'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		11 Dec 2020 15:54:44
User entered 'US'		03 Dec 2020 16:56:04

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:43

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 13:20:22
User entered '9'	System	23 Apr 2021 15:00:45
User entered '8'	System	22 Apr 2021 13:56:24
User entered '7'	System	20 Apr 2021 14:41:28
User entered '6'	System	14 Apr 2021 14:50:11
User entered '5'	System	12 Apr 2021 16:31:12
User entered '4'	System	01 Mar 2021 20:55:44
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '3'	System	22 Feb 2021 15:07:37
User entered '2'	System	11 Dec 2020 15:58:54
User entered '1'	System	03 Dec 2020 16:56:04

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:21:43

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
User entered '11/Dec/2020 10:58'	System	11 Dec 2020 15:58:54

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:21:43

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.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:07:25
DataPoint Verified.		18 Jan 2021 19:05:33
User entered '1'		11 Dec 2020 15:58:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43

SAEID

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'USA-US072-2020-MRNA-1273-P301000015'		03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Yes (Y)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Yes (Y)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'		03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Douglas'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Denham'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered '7940 Floyd Curl Drive'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'San Antonio'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered '78229'	System	03 Dec 2020 16:54:54

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		11 Dec 2020 15:54:44
User entered 'US'		03 Dec 2020 16:56:04

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 13:20:22
User entered '9'	System	23 Apr 2021 15:00:45
User entered '8'	System	22 Apr 2021 13:56:24
User entered '7'	System	20 Apr 2021 14:41:28
User entered '6'	System	14 Apr 2021 14:50:11
User entered '5'	System	12 Apr 2021 16:31:12
User entered '4'	System	01 Mar 2021 20:55:44
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '3'	System	22 Feb 2021 15:07:37
User entered '2'	System	11 Dec 2020 15:58:54
User entered '1'	System	03 Dec 2020 16:56:04

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form (3)
Generated On: 09 Jun 2021 16:21:43
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:00:28
DataPoint Un-verified.		09 Mar 2021 15:50:14
DataPoint Verified.		09 Mar 2021 15:50:02
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '22/Feb/2021 10:07'	System	22 Feb 2021 15:07:37

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:21:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:00:28
DataPoint Un-verified.		09 Mar 2021 15:50:14
DataPoint Verified.		09 Mar 2021 15:50:02
Reviewed for Safety.		01 Mar 2021 20:55:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
User entered '1'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:07:37

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'USA-US072-2020-MRNA-1273-P301000015'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Yes (Y)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Yes (Y)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'		03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Douglas'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Denham'		03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered '7940 Floyd Curl Drive'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'San Antonio'		03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered '78229'	System	03 Dec 2020 16:54:54

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		11 Dec 2020 15:54:44
User entered 'US'		03 Dec 2020 16:56:04

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 13:20:22
User entered '9'	System	23 Apr 2021 15:00:45
User entered '8'	System	22 Apr 2021 13:56:24
User entered '7'	System	20 Apr 2021 14:41:28
User entered '6'	System	14 Apr 2021 14:50:11
User entered '5'	System	12 Apr 2021 16:31:12
User entered '4'	System	01 Mar 2021 20:55:44
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
	(b) (4)	
User entered '3'	System	22 Feb 2021 15:07:37
User entered '2'	System	11 Dec 2020 15:58:54
User entered '1'	System	03 Dec 2020 16:56:04

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form (4)
Generated On: 09 Jun 2021 16:21:43
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:00:32
DataPoint Un-verified.		09 Mar 2021 15:58:03
DataPoint Verified.		09 Mar 2021 15:50:09
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	03 Mar 2021 14:12:23
User entered '01/Mar/2021 15:55'	System	01 Mar 2021 20:55:44

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form (4)
Generated On: 09 Jun 2021 16:21:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:00:32
DataPoint Un-verified.		09 Mar 2021 15:58:03
DataPoint Verified.		09 Mar 2021 15:50:09
User signature succeeded.	(b) (4)	03 Mar 2021 14:12:23
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 20:55:47
User entered '1'		01 Mar 2021 20:55:44

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'USA-US072-2020-MRNA-1273-P301000015'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Yes (Y)'	System	03 Dec 2020 16:54:54

Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Yes (Y)'	System	03 Dec 2020 16:54:54

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

FDA-CBER-2022-1614-1667976

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Douglas'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Denham'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered '7940 Floyd Curl Drive'		03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'San Antonio'		03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered '78229'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		11 Dec 2020 15:54:44
User entered 'US'	System	03 Dec 2020 16:56:04

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 13:20:22
User entered '9'	System	23 Apr 2021 15:00:45
User entered '8'	System	22 Apr 2021 13:56:24
User entered '7'	System	20 Apr 2021 14:41:28
User entered '6'	System	14 Apr 2021 14:50:11
User entered '5'	System	12 Apr 2021 16:31:12
User entered '4'	System	01 Mar 2021 20:55:44
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '3'	System	22 Feb 2021 15:07:37
User entered '2'	System	11 Dec 2020 15:58:54
User entered '1'	System	03 Dec 2020 16:56:04

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:21:43

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:39:53
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:06
User entered '12/Apr/2021 12:31'	(b) (4) System	12 Apr 2021 16:31:12

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:21:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 14:41:19
DataPoint Verified.		19 Apr 2021 17:39:53
User signature succeeded.	(b) (4)	16 Apr 2021 14:03:06
User entered '1'	(b) (4), (b) (6)	12 Apr 2021 16:31:12

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'USA-US072-2020-MRNA-1273-P301000015'		03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Yes (Y)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:43

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Yes (Y)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Douglas'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Denham'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered '7940 Floyd Curl Drive'	System	03 Dec 2020 16:54:54

Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'San Antonio'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered '78229'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		11 Dec 2020 15:54:44
User entered 'US'		03 Dec 2020 16:56:04

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 13:20:22
User entered '9'	System	23 Apr 2021 15:00:45
User entered '8'	System	22 Apr 2021 13:56:24
User entered '7'	System	20 Apr 2021 14:41:28
User entered '6'	System	14 Apr 2021 14:50:11
User entered '5'	System	12 Apr 2021 16:31:12
User entered '4'	System	01 Mar 2021 20:55:44
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '3'	System	22 Feb 2021 15:07:37
User entered '2'	System	11 Dec 2020 15:58:54
User entered '1'	System	03 Dec 2020 16:56:04

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form (6)
Generated On: 09 Jun 2021 16:21:43
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:39:55
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:03:06
User entered '14/Apr/2021 10:50'	(b) (4) System	14 Apr 2021 14:50:11

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:21:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 14:41:19
DataPoint Verified.		19 Apr 2021 17:39:55
User signature succeeded.	(b) (4)	16 Apr 2021 14:03:06
User entered '1'	(b) (4), (b) (6)	14 Apr 2021 14:50:11

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'USA-US072-2020-MRNA-1273-P301000015'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Yes (Y)'	System	03 Dec 2020 16:54:54

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:43

Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'		03 Dec 2020 16:54:54

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:43

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Yes (Y)'	System	03 Dec 2020 16:54:54

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'		03 Dec 2020 16:54:54

FDA-CBER-2022-1614-1668010

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Douglas'	System	03 Dec 2020 16:54:54

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Denham'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered '7940 Floyd Curl Drive'	System	03 Dec 2020 16:54:54

Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'San Antonio'		03 Dec 2020 16:54:54

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered '78229'	System	03 Dec 2020 16:54:54

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		11 Dec 2020 15:54:44
User entered 'US'	System	03 Dec 2020 16:56:04

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 13:20:22
User entered '9'	System	23 Apr 2021 15:00:45
User entered '8'	System	22 Apr 2021 13:56:24
User entered '7'	System	20 Apr 2021 14:41:28
User entered '6'	System	14 Apr 2021 14:50:11
User entered '5'	System	12 Apr 2021 16:31:12
User entered '4'	System	01 Mar 2021 20:55:44
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '3'	System	22 Feb 2021 15:07:37
User entered '2'	System	11 Dec 2020 15:58:54
User entered '1'	System	03 Dec 2020 16:56:04

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form (7)
Generated On: 09 Jun 2021 16:21:43
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:35:20
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:09
User entered '20/Apr/2021 09:41'	(b) (4) System	20 Apr 2021 14:41:28

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:21:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:35:20
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:56:09
User entered '1'	(b) (4), (b) (6)	20 Apr 2021 14:41:28

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:43

SAEID

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'USA-US072-2020-MRNA-1273-P301000015'		03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Yes (Y)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Yes (Y)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Douglas'		03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Denham'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4)	18 Jan 2021 19:05:33
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:55:59
User entered '7940 Floyd Curl Drive'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'San Antonio'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered '78229'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		11 Dec 2020 15:54:44
User entered 'US'	System	03 Dec 2020 16:56:04

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:43

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 13:20:22
User entered '9'	System	23 Apr 2021 15:00:45
User entered '8'	System	22 Apr 2021 13:56:24
User entered '7'	System	20 Apr 2021 14:41:28
User entered '6'	System	14 Apr 2021 14:50:11
User entered '5'	System	12 Apr 2021 16:31:12
User entered '4'	System	01 Mar 2021 20:55:44
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '3'	System	22 Feb 2021 15:07:37
User entered '2'	System	11 Dec 2020 15:58:54
User entered '1'	System	03 Dec 2020 16:56:04

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form (8)
Generated On: 09 Jun 2021 16:21:43
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:35:22
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:47:09
User entered '22/Apr/2021 09:56'	System	22 Apr 2021 13:56:24

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:21:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 13:20:09
DataPoint Verified.		22 Apr 2021 18:35:22
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:09
User entered '1'	(b) (4), (b) (6)	22 Apr 2021 13:56:24

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'USA-US072-2020-MRNA-1273-P301000015'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Yes (Y)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Yes (Y)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Douglas'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Denham'	System	03 Dec 2020 16:54:54

PRODUCTION RELEASE (v12.003
EAB) (1725)

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered '7940 Floyd Curl Drive'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'San Antonio'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered '78229'		03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		11 Dec 2020 15:54:44
User entered 'US'		03 Dec 2020 16:56:04

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:43

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 13:20:22
User entered '9'	System	23 Apr 2021 15:00:45
User entered '8'	System	22 Apr 2021 13:56:24
User entered '7'	System	20 Apr 2021 14:41:28
User entered '6'	System	14 Apr 2021 14:50:11
User entered '5'	System	12 Apr 2021 16:31:12
User entered '4'	System	01 Mar 2021 20:55:44
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '3'	System	22 Feb 2021 15:07:37
User entered '2'	System	11 Dec 2020 15:58:54
User entered '1'	System	03 Dec 2020 16:56:04

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 16:21:43

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:30:34
User entered '23/Apr/2021 11:00'	System	23 Apr 2021 15:00:45

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 16:21:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 13:20:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:32:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:30:34
User entered '1'		23 Apr 2021 15:00:45

SAEID

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'USA-US072-2020-MRNA-1273-P301000015'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Yes (Y)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:43

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'		03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:55:59
User entered 'Yes (Y)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'No (N)'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Douglas'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'Denham'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered '7940 Floyd Curl Drive'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered 'San Antonio'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		03 Dec 2020 16:55:59
User entered '78229'	System	03 Dec 2020 16:54:54

US3292127
Folder: SAE USA-US072-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:05:33
Reviewed for Safety.		11 Dec 2020 15:54:44
User entered 'US'	System	03 Dec 2020 16:56:04

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:43

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '10'	System	29 Apr 2021 13:20:22
User entered '9'	System	23 Apr 2021 15:00:45
User entered '8'	System	22 Apr 2021 13:56:24
User entered '7'	System	20 Apr 2021 14:41:28
User entered '6'	System	14 Apr 2021 14:50:11
User entered '5'	System	12 Apr 2021 16:31:12
User entered '4'	System	01 Mar 2021 20:55:44
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 18:47:45
User entered '3'	System	22 Feb 2021 15:07:37
User entered '2'	System	11 Dec 2020 15:58:54
User entered '1'	System	03 Dec 2020 16:56:04

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 16:21:43

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:25:56
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
User entered '29/Apr/2021 06:20'	(b) (4) System	29 Apr 2021 13:20:22

US3292127

Folder: SAE USA-US072-2020-MRNA-1273-P301000015

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 16:21:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:25:56
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:32
User entered '1'	(b) (4), (b) (6)	29 Apr 2021 13:20:22

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:02:28
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered 'USA-US072-2021-MRNA-1273-P301000012'	System	01 Feb 2021 17:44:26

Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:08
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered 'Yes (Y)'	System	01 Feb 2021 17:44:26

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:10
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered 'No (N)'	System	01 Feb 2021 17:44:26

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered 'No (N)'	System	01 Feb 2021 17:44:26

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:17
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered 'Yes (Y)'	System	01 Feb 2021 17:44:26

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:19
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered 'No (N)'	System	01 Feb 2021 17:44:26

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:21
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered 'No (N)'	System	01 Feb 2021 17:44:26

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered 'No (N)'	System	01 Feb 2021 17:44:26

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:26
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered 'Douglas'	System	01 Feb 2021 17:44:26

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43

Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:28
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered 'Denham'	System	01 Feb 2021 17:44:26

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered '7940 Floyd Curl Drive'	System	01 Feb 2021 17:44:26

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:32
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered 'San Antonio'	System	01 Feb 2021 17:44:26

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered '78229'	System	01 Feb 2021 17:44:26

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered 'US'	System	01 Feb 2021 17:45:22

US3292127

Folder: SAE USA-US072-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:43

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
User entered '1'	System	01 Feb 2021 17:45:22

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:02:28
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered 'USA-US072-2021-MRNA-1273-P301000012'	System	01 Feb 2021 17:44:26

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:08
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered 'Yes (Y)'	System	01 Feb 2021 17:44:26

US3292127

Folder: SAE USA-US072-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:43

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:10
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered 'No (N)'	System	01 Feb 2021 17:44:26

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered 'No (N)'	System	01 Feb 2021 17:44:26

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:17
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered 'Yes (Y)'	System	01 Feb 2021 17:44:26

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:19
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered 'No (N)'	System	01 Feb 2021 17:44:26

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:21
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered 'No (N)'	System	01 Feb 2021 17:44:26

US3292127

Folder: SAE USA-US072-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:21:43

Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered 'No (N)'	System	01 Feb 2021 17:44:26

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:26
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered 'Douglas'	System	01 Feb 2021 17:44:26

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:28
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered 'Denham'	System	01 Feb 2021 17:44:26

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered '7940 Floyd Curl Drive'	System	01 Feb 2021 17:44:26

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:32
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered 'San Antonio'	System	01 Feb 2021 17:44:26

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered '78229'	System	01 Feb 2021 17:44:26

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43

Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:01:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered 'US'	System	01 Feb 2021 17:45:22

US3292127
Folder: SAE USA-US072-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 16:21:43
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
	(b) (4)	
User entered '1'	System	01 Feb 2021 17:45:22

US3292127

Folder: SAE USA-US072-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:21:43

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:00:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
User entered '01/Feb/2021 12:45'	(b) (4) System	01 Feb 2021 17:45:22

US3292127

Folder: SAE USA-US072-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:21:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:00:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:47:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:45:27
User entered '1'		01 Feb 2021 17:45:22