US3522269 (Prod: Henry Ford Health System)

Generated By: KC Joubran

Generated On: 10 Jun 2021 07:58:05

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US3522269
Form: Participant Creation
Data signed: (b) (4) **21 Feb 2021 21:06:14**
Generated On: 10 Jun 2021 07:58:05

Participant ID US3522269

mRNA-1273-P301 Completion Guidelines

US3522269

Folder: Screening

Form: Visit Date

Data signed: (b) (4) **21 Feb 2021 21:06:15**

Generated On: 10 Jun 2021 07:58:05

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	SCRN

US3522269

Folder: Screening

Form: Demographics

Data signed: (b) (4) **21 Feb 2021 21:06:15**

Generated On: 10 Jun 2021 07:58:05

Date of Birth (MMM yyyy)	(b) (6) 1976
Age	44
Age Units	YEARS
Age (Derived)	44
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) **21 Feb 2021 21:06:15**

Generated On: 10 Jun 2021 07:58:05

Date of Informed Consent *(dd MMM yyyy)*	21 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) **21 Feb 2021 21:06:15**

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Did the participant meet all eligibility criteria?   Yes ⬤

                                                             No ◯

Were any significant conditions reported?   Yes ◯

                                                             No ⬤

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) **21 Feb 2021 21:06:15**

Generated On: 10 Jun 2021 07:58:05

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	21 AUG 2020
Time of assessment *(00:00-23:59)*	08:26 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 08:26
Height *(xxx.x)*	62 in
Weight *(xxx.x)*	120.8 lb
BMI *(xxx.x)*	22.14081 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) **21 Feb 2021 21:06:15**

Generated On: 10 Jun 2021 07:58:05

Was the physical examination performed?   Yes ●

                                                                            No ◯

Date of examination *(dd MMM yyyy)*   21 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: Childbearing Potential

Data signed: (b) (4) **21 Feb 2021 21:06:15**

Generated On: 10 Jun 2021 07:58:05

Date of assessment *(dd MMM yyyy)*	21 AUG 2020
Is the participant of childbearing potential?	Yes ●
	No ○
If No, what is the reason?	Surgically sterile ○
	Post-menopausal ○
	Partner medically sterile ○
	Not reached age of Menarche ○
	Other ○
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery *(dd MMM yyyy)*	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	
Date of last menstruation unknown	False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) **21 Feb 2021 21:06:15**

Generated On: 10 Jun 2021 07:58:05

Was the pregnancy test performed?	Yes ●
	No ○
Date of test *(dd MMM yyyy)*	21 AUG 2020
Test performed	Urine ●
	Serum ○
Result	Positive ○
	Negative ●
Was FSH sample collected?	Yes ○
	No ●
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **21 Feb 2021 21:06:15**

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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	True
Resides in Nursing Home or Assisted Living Facility	False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **21 Feb 2021 21:06:15**

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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)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) **16 Feb 2021 18:36:16**

Generated On: 10 Jun 2021 07:58:05

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	21 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) **16 Feb 2021 18:36:16**

Generated On: 10 Jun 2021 07:58:05

What was the date of randomization? *(dd MMM yyyy)*	21 AUG 2020
What was the participant's randomization number?	106826

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) **16 Feb 2021 18:36:16**

Generated On: 10 Jun 2021 07:58:05

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) **16 Feb 2021 18:36:16**

Generated On: 10 Jun 2021 07:58:05

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)*	21 AUG 2020
Time of assessment *(00:00-23:59)*	08:26 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 08:26
Temperature *(xxx.x)*	97.7 F
Route of measurement	Oral ◯
	Axillary ◯
	Other ⬤
If Other, specify	TEMPORAL
Pulse *(xxx)*	81 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **16 Feb 2021 18:36:16**

Generated On: 10 Jun 2021 07:58:05

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)*	21 AUG 2020
Time of assessment *(00:00-23:59)*	10:05 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 10:05
Temperature *(xxx.x)*	98.1 F
Route of measurement	Oral ○
	Axillary ○
	Other ⬤
If Other, specify	TEMPORAL
Pulse *(xxx)*	76 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) **16 Feb 2021 18:36:16**

Generated On: 10 Jun 2021 07:58:05

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 1 Day 1
Form: Pregnancy Test
Data signed: (b) (4) **16 Feb 2021 18:36:16**
Generated On: 10 Jun 2021 07:58:05

Was the pregnancy test performed? Yes ◯

No ⬤

Date of test *(dd MMM yyyy)* _____

Test performed Urine ◯

Serum ◯

Result Positive ◯

Negative ◯

Was FSH sample collected? Yes ◯

No ⬤

Collection date _____

Collection time _____

Collection date and time (derived) _____

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)*	21 AUG 2020
What was the treatment time? *(00:00-23:59)*	09:35 (24 HR)
Treatment Date and Time (derived)	21 AUG 2020 09:35
Which arm was used to give treatment?	Left Arm ⬤
	Right Arm ◯
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) **16 Feb 2021 18:36:16**

Generated On: 10 Jun 2021 07:58:05

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	21 AUG 2020
Collection time *(00:00-23:59)*	09:13 (24 HR)
Collection date and time (derived)	21 AUG 2020 09:13

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **16 Feb 2021 18:36:16**

Generated On: 10 Jun 2021 07:58:05

Collection date *(dd MMM yyyy)*   21 AUG 2020

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:15	21 AUG 2020 09:15
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) **16 Feb 2021 18:36:16**

Generated On: 10 Jun 2021 07:58:05

Is the participant continuing to the next visit?   Yes ●

                                                                                          No ◯

Continuing Flag   1

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	21 AUG 2020 10:06
PC Open Date & Time	21 AUG 2020 09:55
PC Close Date & Time	21 AUG 2020 12:25

FDA-CBER-2022-1614-0828959

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	21 AUG 2020 16:44
PC Open Date & Time	21 AUG 2020 13:20
PC Close Date & Time	22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.7 °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	22 AUG 2020 16:04
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3522269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 07:58:05

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	23 AUG 2020 12:04
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

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**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	24 AUG 2020 13:40
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT	DAY 5

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

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

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

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

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

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

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

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

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

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	25 AUG 2020 12:04
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

FDA-CBER-2022-1614-0828964

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:05

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**	98.4 °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	26 AUG 2020 13:08
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

TIMEPOINT	DAY 7

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	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	27 AUG 2020 13:05
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

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	21 AUG 2020 11:35
PC Open Date & Time	21 AUG 2020 09:55
PC Close Date & Time	21 AUG 2020 12:25

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

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	21 AUG 2020 16:44
PC Open Date & Time	21 AUG 2020 13:20
PC Close Date & Time	22 AUG 2020 11:59

FDA-CBER-2022-1614-0828968

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	22 AUG 2020 16:04
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:05

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	23 AUG 2020 12:04
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:05

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	24 AUG 2020 13:40
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3522269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 07:58:05

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 ○
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	2
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ●
	No ○
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	5
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	25 AUG 2020 12:06
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3522269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 07:58:05

TIMEPOINT	DAY 6

Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ○
	Does not interfere with activity ●
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ●
	No ○
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	3
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.	3
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	26 AUG 2020 13:10
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:05

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	27 AUG 2020 13:06
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:58:05

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	◯

FDA-CBER-2022-1614-0828975

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

PC Time stamp	21 AUG 2020 11:36
PC Open Date & Time	21 AUG 2020 09:55
PC Close Date & Time	21 AUG 2020 12:25

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:58:05

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 ○

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:58:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	21 AUG 2020 16:45
PC Open Date & Time	21 AUG 2020 13:20
PC Close Date & Time	22 AUG 2020 11:59

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:58:05

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	22 AUG 2020 16:05
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:58:05

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	23 AUG 2020 12:05
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:58:05

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	24 AUG 2020 13:41
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT	DAY 5

HEADACHE

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

FATIGUE

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

MUSCLE ACHES ALL OVER BODY

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

JOINT ACHES IN SEVERAL JOINTS

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

NAUSEA/VOMITING

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

CHILLS

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

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

	Yes ◯
PC Time stamp	25 AUG 2020 12:07
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:58:05

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	26 AUG 2020 13:11
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:58:05

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	27 AUG 2020 13:06
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT	DAY 8
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 ◯

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

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT	DAY 9
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 ◯

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

US3522269

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT	DAY 8
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ◯ Yes ◯

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

US3522269

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT	DAY 9
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ◯ Yes ◯

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

US3522269

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) **16 Feb 2021 18:36:12**

Generated On: 10 Jun 2021 07:58:05

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	28 AUG 2020
Please select one status for the follow-up contact	Contact Made ○
	Contact Not Made ●
Comments	ATTEMPTED TO REACH PATIENT WITH NO SUCCESS.
If Contact Not Made, please provide Comments	WILL ATTEMPT AT LATER TIME.

US3522269

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **16 Feb 2021 18:36:12**

Generated On: 10 Jun 2021 07:58:05

Is the participant continuing to the next visit?   Yes ●

                                                                                     No ○

Continuing Flag   1

US3522269

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) **16 Feb 2021 18:36:12**

Generated On: 10 Jun 2021 07:58:05

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	04 SEP 2020
Please select one status for the follow-up contact	Contact Made ○
	Contact Not Made ●
Comments	CONTACT NOT MADE; VOICEMAIL LEFT
If Contact Not Made, please provide Comments	

US3522269

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **16 Feb 2021 18:36:12**

Generated On: 10 Jun 2021 07:58:05

Is the participant continuing to the next visit?　　　　　　　　　　　Yes ●

No ○

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　　1

US3522269

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) **16 Feb 2021 18:36:12**

Generated On: 10 Jun 2021 07:58:05

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	1ST ATTEMPT 11 SEP 2020; 2ND ATTEMPT 15 SEP 2020; 3RD
If Contact Not Made, please provide Comments	ATTEMPT 16 SEP 2020

US3522269

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **16 Feb 2021 18:36:12**

Generated On: 10 Jun 2021 07:58:05

Is the participant continuing to the next visit?   Yes ⬤

                                                                   No ◯

Continuing Flag   1

US3522269

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) **16 Feb 2021 18:36:16**

Generated On: 10 Jun 2021 07:58:05

Was this visit performed?	Yes ⬤
	No ◯
Visit date (dd MMM yyyy)	22 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤
Folder OID	VISIT2

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **16 Feb 2021 18:36:16**

Generated On: 10 Jun 2021 07:58:05

Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	22 SEP 2020
Time of assessment *(00:00-23:59)*	13:47 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 13:47
Temperature *(xxx.x)*	98.3 F
Route of measurement	Oral ○
	Axillary ○
	Other ●
If Other, specify	TEMPORAL
Pulse *(xxx)*	86 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	65 mmHg
Diastolic Blood Pressure units	MMHG

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **16 Feb 2021 18:36:16**

Generated On: 10 Jun 2021 07:58:05

Timepoint	Pre-Dose ⭘
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ⭘
Date of assessment *(dd MMM yyyy)*	22 SEP 2020
Time of assessment *(00:00-23:59)*	14:45 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 14:45
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ⭘
	Axillary ⭘
	Other ⬤
If Other, specify	TEMPORAL
Pulse *(xxx)*	84 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG

US3522269

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **16 Feb 2021 18:36:16**

Generated On: 10 Jun 2021 07:58:05

Was the physical examination performed?   Yes ●

                                                            No ○

Date of examination *(dd MMM yyyy)*   22 SEP 2020

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

US3522269

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) **16 Feb 2021 18:36:16**

Generated On: 10 Jun 2021 07:58:05

Was the pregnancy test performed?	Yes ⬤
	No ◯
Date of test *(dd MMM yyyy)*	22 SEP 2020
Test performed	Urine ⬤
	Serum ◯
Result	Positive ◯
	Negative ⬤
Was FSH sample collected?	Yes ◯
	No ⬤
Collection date	
Collection time	
Collection date and time (derived)	

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)*	22 SEP 2020
What was the treatment time? *(00:00-23:59)*	14:15 (24 HR)
Treatment Date and Time (derived)	22 SEP 2020 14:15
Which arm was used to give treatment?	Left Arm ●
	Right Arm ○
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **16 Feb 2021 18:36:16**

Generated On: 10 Jun 2021 07:58:05

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	22 SEP 2020
Collection time *(00:00-23:59)*	14:10 (24 HR)
Collection date and time (derived)	22 SEP 2020 14:10

US3522269

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **16 Feb 2021 18:36:16**

Generated On: 10 Jun 2021 07:58:05

Collection date *(dd MMM yyyy)*			22 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:12	22 SEP 2020 14:12
Nasopharyngeal Swab 2	No		

US3522269

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) **16 Feb 2021 18:36:16**

Generated On: 10 Jun 2021 07:58:05

Is the participant continuing to the next visit?   Yes ●

                                                                        No ○

Continuing Flag   1

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ● No ○
Please record your **TEMPERATURE in °F**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○ No ●

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

PC Time Stamp	22 SEP 2020 14:51
PC Open Date & Time	22 SEP 2020 13:35
PC Close Date & Time	22 SEP 2020 16:05

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**	99.0 °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	22 SEP 2020 18:57
PC Open Date & Time	22 SEP 2020 17:00
PC Close Date & Time	23 SEP 2020 11:59

FDA-CBER-2022-1614-0829011

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:05

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**	98.3 °F

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

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

PC Time Stamp	23 SEP 2020 12:27
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

FDA-CBER-2022-1614-0829012

TIMEPOINT	DAY 3

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	98.8 °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	24 SEP 2020 12:57
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:05

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	25 SEP 2020 12:38
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:05

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**	98.7 °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	26 SEP 2020 12:05
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

TIMEPOINT	DAY 6

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	98.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	27 SEP 2020 12:36
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.6 °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	28 SEP 2020 12:04
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

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	22 SEP 2020 14:51
PC Open Date & Time	22 SEP 2020 13:35
PC Close Date & Time	22 SEP 2020 16:05

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

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	22 SEP 2020 18:58
PC Open Date & Time	22 SEP 2020 17:00
PC Close Date & Time	23 SEP 2020 11:59

FDA-CBER-2022-1614-0829019

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	23 SEP 2020 12:27
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:05

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	24 SEP 2020 12:58
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

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	25 SEP 2020 12:38
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:05

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	26 SEP 2020 12:05
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:05

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

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:05

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	28 SEP 2020 12:04
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:58:05

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
HEADACHE	None ●
	No interference with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
FATIGUE	None ●
	No interference with activity ○
	Some interference with activity ○
	Significant; prevents daily activity ○
MUSCLE ACHES ALL OVER BODY	None ●
	No interference with activity ○
	Some interference with activity ○
	Significant; prevents daily activity ○
JOINT ACHES IN SEVERAL JOINTS	None ●
	No interference with activity ○
	Some interference with activity ○
	Significant; prevents daily activity ○
NAUSEA/VOMITING	None ●
	No interference with activity or 1-2 episodes/24 hours ○
	Some interference with activity or >2 episodes/24 hours ○
	Prevents daily activity, requires outpatient IV hydration ○
CHILLS	None ●
	No interference with activity ○
	Some interference with activity not requiring medical attention ○
	Prevents daily activity and requires medical attention ○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤
	Yes ◯
PC Time stamp	22 SEP 2020 14:51
PC Open Date & Time	22 SEP 2020 13:35
PC Close Date & Time	22 SEP 2020 16:05

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:58:05

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
HEADACHE	None ◯
	No interference with activity ⬤
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
FATIGUE	None ◯
	No interference with activity ⬤
	Some interference with activity ◯
	Significant; prevents daily activity ◯
MUSCLE ACHES ALL OVER BODY	None ⬤
	No interference with activity ◯
	Some interference with activity ◯
	Significant; prevents daily activity ◯
JOINT ACHES IN SEVERAL JOINTS	None ⬤
	No interference with activity ◯
	Some interference with activity ◯
	Significant; prevents daily activity ◯
NAUSEA/VOMITING	None ⬤
	No interference with activity or 1-2 episodes/24 hours ◯
	Some interference with activity or >2 episodes/24 hours ◯
	Prevents daily activity, requires outpatient IV hydration ◯
CHILLS	None ⬤
	No interference with activity ◯
	Some interference with activity not requiring medical attention ◯
	Prevents daily activity and requires medical attention ◯

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

PC Time stamp	22 SEP 2020 18:58
PC Open Date & Time	22 SEP 2020 17:00
PC Close Date & Time	23 SEP 2020 11:59

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	23 SEP 2020 12:27
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:58:05

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	24 SEP 2020 12:58
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

FDA-CBER-2022-1614-0829033

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:58:05

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	25 SEP 2020 12:38
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

TIMEPOINT	DAY 5

HEADACHE

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

FATIGUE

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

MUSCLE ACHES ALL OVER BODY

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

JOINT ACHES IN SEVERAL JOINTS

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

NAUSEA/VOMITING

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

CHILLS

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

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

	Yes ⭕
PC Time stamp	26 SEP 2020 12:06
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:58:05

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

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:05

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	28 SEP 2020 12:05
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3522269
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **16 Feb 2021 18:36:12**
Generated On: 10 Jun 2021 07:58:05

Was Contact Attempted?   Yes ●

                                                                          No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*   29 SEP 2020

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

                                                      Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3522269

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) **16 Feb 2021 18:36:12**

Generated On: 10 Jun 2021 07:58:05

Is the participant continuing to the next visit?   Yes ●

                                                                      No ○

Continuing Flag   1

US3522269

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) **16 Feb 2021 18:36:12**

Generated On: 10 Jun 2021 07:58:05

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 07 OCT 2020 |

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

Comments

If Contact Not Made, please provide Comments

FLU VACCINE RECEIVED 05 OCT 2020. NO ONGOING OR NEW AE REPORTED, NO NEW ILLNESS OR HOSPITAL VISITS; NO CHANGES IN HEALTH STATUS, MEDICATIONS, COVID-19 EXPOSURE OR PREGNANCY RISK

US3522269

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **16 Feb 2021 18:36:12**

Generated On: 10 Jun 2021 07:58:05

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3522269

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) **16 Feb 2021 18:36:12**

Generated On: 10 Jun 2021 07:58:05

Was Contact Attempted?	Yes ⬤
	No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*	13 OCT 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3522269

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) **16 Feb 2021 18:36:12**

Generated On: 10 Jun 2021 07:58:05

Is the participant continuing to the next visit?   Yes ●

                                                                    No ◯

Continuing Flag   1

US3522269

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) **16 Feb 2021 18:36:17**

Generated On: 10 Jun 2021 07:58:05

Was this visit performed?	Yes ◯
	No ●

Visit date (dd MMM yyyy)

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

Folder OID   VISIT3

US3522269

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) **16 Feb 2021 18:36:17**

Generated On: 10 Jun 2021 07:58:05

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) _____

US3522269

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) **16 Feb 2021 18:36:17**

Generated On: 10 Jun 2021 07:58:05

Was the physical examination performed?   Yes ◯

                                                      No ⬤

Date of examination *(dd MMM yyyy)* _____

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

Was the sample collected?   Yes ◯

                                                                             No ⬤

Collection date *(dd MMM yyyy)*

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

Collection date and time (derived)

US3522269
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **16 Feb 2021 18:36:16**
Generated On: 10 Jun 2021 07:58:05

Is the participant continuing to the next visit?   Yes ◯

                                                                                          No ⬤

Continuing Flag

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT	DAY 64

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

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

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

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

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

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-2022-1614-0829053

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT	**DAY 71**

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

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

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

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

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05

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

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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-2022-1614-0829059

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3522269

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 07:58:05

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

US3522269
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 10 Jun 2021 07:58:05

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 ◯

Was this visit performed?   Yes ⃝

                                                             No ⃝

Visit date (dd MMM yyyy)

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

                                                             Clinic ⃝

Folder OID

US3522269

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

Form: Unblinding

Generated On: 10 Jun 2021 07:58:05

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

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)*	

Participant randomization assignment	mRNA-1273 ◯
	Placebo ◯

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

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

Will participant receive mRNA-1273?	Yes ◯
	No ◯

Placebo Only Flag	
Continuing with mRNA-1273	

Was the sample collected?   Yes ◯

                                                                     No ◯

Collection date *(dd MMM yyyy)*

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

Collection date and time (derived)

| Was the sample collected? | Yes ⭕ |
| | No ⭕ |

Collection date *(dd MMM yyyy)*	
Collection time *(00:00 - 23:59)*	
Collection Date and Time (derived)	

US3522269

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **21 Feb 2021 21:06:14**

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Did the participant experience any adverse events?   Yes ●

                                                                              No ◯

If Yes, enter details on the Adverse Events form.

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **21 Feb 2021 21:06:14**

Generated On: 10 Jun 2021 07:58:05

AEID	USA-US131-2020-MRNA-1273-P30 1000005
Adverse event	NAUSEA
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)*	7 SEP 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ○
	No ●
If not Ongoing, end date *(dd MMM yyyy)*	15 SEP 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ○
	Grade 2/Moderate ○
	Grade 3/Severe ○
	Grade 4 ●
Is the adverse event serious?	Yes ●
	No ○

AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	12 SEP 2020
Hospital Discharge Date *(dd MMM yyyy)*	16 SEP 2020
Admitted to ICU?	Yes ○
	No ●
	Unknown ○

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

Relationship to investigational product

Not Related ⬤
Related ◯
Not Applicable ◯

Relationship to Study Procedure

Not Related ⬤
Related ◯
Not Applicable ◯

Action taken with investigational product

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

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	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

FDA-CBER-2022-1614-0829070

NAUSEA ONSET 7-SEP-2020, GRADUAL AND GOT WORSE OVER THE FOLLOWING DAYS, VOMITING AND ABDOMINAL PAIN STARTED 8-SEP-2020, AND GOT WORSE THE NEXT FEW DAYS. SHE DROVE HERSELF TO THE WINDSOR REGIONAL HOSPITAL ON 11-SEP-2020 OR 12-SEP-2020, SHE COULD NOT REMEMBER THE DATE. AT THE TIME, THE VOMITING WAS SEVERE, SHE VOMITED ANY TIME THAT SHE TRIED TO EAT SOMETHING, AT LEAST 5-10 TIMES THAT DAY, AND WAS DRY HEAVING AT SEVERAL OTHER POINTS

THE HOSPITAL WAS CONCERNED ABOUT GALLSTONES. SHE HAD AN ULTRASOUND 11-SEP-2020 OR 12-SEP-2020 AND THEN SHE HAD TO WAIT TO GET THE MRCP UNTIL 12-SEP-2020 OR 13-SEP-2020, BUT THE RESULTS CAME BACK SHOWING NO GALLSTONES. THEY DID FIND THAT SHE HAD DILATED BILE DUCTS. SHE ALSO HAD A LOW POTASSIUM AND MAGNESIUM FROM THE VOMITING. SHE WAS GIVEN IV REPLACEMENT. OVER THE NEXT DAY OR TWO,

HER VOMITING AND NAUSEA RESOLVED, AND LIQUID THEN SOLID FOOD WAS REINTRODUCED AND TOLERATED OK.SHE WAS DISCHARGED 16-SEP-2020. THEY DID NOT DISCHARGE HER ON ANY CHRONIC OR ONGOING MEDICATIONS. THE NAUSEA AND VOMITING HAD COMPLETELY RESOLVED AT THAT POINT.

ZOFRAN 1 TAB PO AS NEEDED, START DATE 9/12/20- STOP DATE 9/14/20 (APPROXIMATE DATES)

MORPHINE 1 TAB PO AS NEEDED, START DATE 9/12/20- STOP DATE 9/13/20 (APPROXIMATE DATES)

PROTONIX, 1 TAB PO DAILY, START DATE 9/12/20- STOP DATE 9/16/20 (APPROXIMATE DATES)

POTASSIUM, IV, AS NEEDED, START DATE 9/12/20- STOP DATE 9/13/20 (APPROXIMATE DATES)

MAGNESIUM IV, AS NEEDED, START DATE 9/12/20- STOP DATE 9/13/20 (APPROXIMATE DATES)

CALCIUM 1 TAB PO DAILY, START DATE 9/14/20- STOP DATE 9/16/20

FDA-CBER-2022-1614-0829072

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **21 Feb 2021 21:06:14**

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	(APPROXIMATE DATES)
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

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) **21 Feb 2021 21:06:14**

Generated On: 10 Jun 2021 07:58:05

AEID	USA-US131-2020-MRNA-1273-P30 1000005
Adverse event	ABDOMINAL PAIN

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

| Was this a Solicited Adverse Reaction? | Yes ◯ |
| | No ⬤ |

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

Start date *(dd MMM yyyy)*	8 SEP 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	

| Ongoing? | Yes ◯ |
| | No ⬤ |

If not Ongoing, end date *(dd MMM yyyy)*	15 SEP 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

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

| Is the adverse event serious? | Yes ⬤ |
| | No ◯ |

AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	12 SEP 2020
Hospital Discharge Date *(dd MMM yyyy)*	16 SEP 2020
Admitted to ICU?	Yes ◯
	No ⬤
	Unknown ◯

FDA-CBER-2022-1614-0829074

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

FDA-CBER-2022-1614-0829075

VOMITING AND ABDOMINAL PAIN STARTED 8-SEP-2020, AND GOT WORSE THE NEXT FEW DAYS. SHE DROVE HERSELF TO THE WINDSOR REGIONAL HOSPITAL ON 11-SEP-2020 OR 12-SEP-2020, SHE COULD NOT REMEMBER THE DATE. AT THE TIME, THE VOMITING WAS SEVERE, SHE VOMITED ANY TIME THAT SHE TRIED TO EAT SOMETHING, AT LEAST 5-10 TIMES THAT DAY, AND WAS DRY HEAVING AT SEVERAL OTHER POINTS

THE HOSPITAL WAS CONCERNED ABOUT GALLSTONES. SHE HAD AN ULTRASOUND 11-SEP-2020 OR 12-SEP-2020 AND THEN SHE HAD TO WAIT TO GET THE MRCP UNTIL 12-SEP-2020 OR 13-SEP-2020, BUT THE RESULTS CAME BACK SHOWING NO GALLSTONES. THEY DID FIND THAT SHE HAD DILATED BILE DUCTS. SHE ALSO HAD A LOW POTASSIUM AND MAGNESIUM FROM THE VOMITING. SHE WAS GIVEN IV REPLACEMENT. OVER THE NEXT DAY OR TWO, HER VOMITING AND NAUSEA RESOLVED, AND LIQUID THEN SOLID FOOD WAS

	REINTRODUCED AND TOLERATED OK. SHE WAS DISCHARGED 16-SEP-2020. THEY DID NOT DISCHARGE HER ON ANY CHRONIC OR ONGOING MEDICATIONS. THE NAUSEA AND VOMITING HAD COMPLETELY RESOLVED AT THAT POINT.
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

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) **21 Feb 2021 21:06:14**

Generated On: 10 Jun 2021 07:58:05

AEID	USA-US131-2020-MRNA-1273-P30 1000005
Adverse event	VOMITING

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

Ongoing? — Yes ○ No ●

If not Ongoing, end date *(dd MMM yyyy)*	15 SEP 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

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

Is the adverse event serious? — Yes ● No ○

AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	12 SEP 2020
Hospital Discharge Date *(dd MMM yyyy)*	16 SEP 2020

Admitted to ICU? — Yes ○ No ● Unknown ○

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) **21 Feb 2021 21:06:14**

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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

VOMITING AND ABDOMINAL PAIN STARTED 8-SEP-2020, AND GOT WORSE THE NEXT FEW DAYS. SHE DROVE HERSELF TO THE WINDSOR REGIONAL HOSPITAL ON 11-SEP-2020 OR 12-SEP-2020, SHE COULD NOT REMEMBER THE DATE. AT THE TIME, THE VOMITING WAS SEVERE, SHE VOMITED ANY TIME THAT SHE TRIED TO EAT SOMETHING, AT LEAST 5-10 TIMES THAT DAY, AND WAS DRY HEAVING AT SEVERAL OTHER POINTS

THE HOSPITAL WAS CONCERNED ABOUT GALLSTONES. SHE HAD AN ULTRASOUND 11-SEP-2020 OR 12-SEP-2020 AND THEN SHE HAD TO WAIT TO GET THE MRCP UNTIL 12-SEP-2020 OR 13-SEP-2020, BUT THE RESULTS CAME BACK SHOWING NO GALLSTONES. THEY DID FIND THAT SHE HAD DILATED BILE DUCTS. SHE ALSO HAD A LOW POTASSIUM AND MAGNESIUM FROM THE VOMITING. SHE WAS GIVEN IV REPLACEMENT. OVER THE NEXT DAY OR TWO, HER VOMITING AND NAUSEA RESOLVED, AND LIQUID THEN SOLID FOOD WAS

REINTRODUCED AND TOLERATED OK.SHE WAS DISCHARGED 16-SEP-2020. THEY DID NOT DISCHARGE HER ON ANY CHRONIC OR ONGOING MEDICATIONS. THE NAUSEA AND VOMITING HAD COMPLETELY RESOLVED AT THAT POINT.
ZOFRAN 1 TAB PO AS NEEDED, START DATE 9/12/20- STOP DATE 9/14/20 (APPROXIMATE DATES)
MORPHINE 1 TAB PO AS NEEDED, START DATE 9/12/20- STOP DATE 9/13/20 (APPROXIMATE DATES)
PROTONIX, 1 TAB PO DAILY, START DATE 9/12/20- STOP DATE 9/16/20 (APPROXIMATE DATES)
POTASSIUM, IV, AS NEEDED, START DATE 9/12/20- STOP DATE 9/13/20 (APPROXIMATE DATES)
MAGNESIUM IV, AS NEEDED, START DATE 9/12/20- STOP DATE 9/13/20 (APPROXIMATE DATES)
CALCIUM 1 TAB PO DAILY, START DATE 9/14/20- STOP DATE 9/16/20 (APPROXIMATE DATES)

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

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **21 Feb 2021 21:06:14**

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

No ◯

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

Name of Medication	ZOFRAN

Prophylaxis	Yes ⚪
	No ⚫

Indication	NAUSEA

Dose per administration	UNKNOWN

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

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) **21 Feb 2021 21:06:14**

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Name of Medication	MORPHINE

Prophylaxis

Yes ⭕

No ⬤

Indication	ABDOMINAL PAIN
Dose per administration	UNKNOWN

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)

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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)*	12 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ⭘
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	13 SEP 2020
Was this medication taken for solicited event?	Yes ⭘
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ⭘
	803 ⭘
	804 ⭘

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) **21 Feb 2021 21:06:14**

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Name of Medication	PANTOPRAZOLE

Prophylaxis	
Yes	⚪
No	⚫

Indication	NAUSEA
Dose per administration	UNKNOWN

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)*	12 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	16 SEP 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

FDA-CBER-2022-1614-0829088

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) **21 Feb 2021 21:06:14**

Generated On: 10 Jun 2021 07:58:05

Name of Medication	POTASSIUM IV
Prophylaxis	Yes ◯
	No ⬤
Indication	ELECTROLYTE REPLACEMENT FOR VOMITING
Dose per administration	UNKNOWN
Dose unit	mg ◯
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ⬤
If dose unit is Other, specify	IV BAG
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)*	12 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	13 SEP 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) **21 Feb 2021 21:06:14**

Generated On: 10 Jun 2021 07:58:05

Name of Medication	MAGNESIUM IV

Prophylaxis

Yes ⭕

No ⬤

Indication	ELECTROLYTE REPLACEMENT FOR VOMITING
Dose per administration	UNKNOWN

Dose unit

mg ⭕

ug ⭕

mL ⭕

g ⭕

IU ⭕

tablet ⭕

capsule ⭕

puff ⭕

Other ⬤

If dose unit is Other, specify	IV DRIP

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)*	12 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤

If not Ongoing, End date *(dd MMM yyyy)*	13 SEP 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤

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

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) **21 Feb 2021 21:06:14**

Generated On: 10 Jun 2021 07:58:05

Name of Medication	CALCIUM

Prophylaxis	Yes ⚪
	No ⚫

Indication	ELECTROLYTE REPLACEMENT FOR VOMITING

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)*	14 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	16 SEP 2020
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	INFLUENZA VACCINE

Prophylaxis	Yes ●
	No ○

Indication	FLU VACCINATION

Dose per administration	0.5

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

If dose unit is Other, specify	

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

If frequency is Other, specify	

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

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **21 Feb 2021 21:06:14**
Generated On: 10 Jun 2021 07:58:05

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	5 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤

If not Ongoing, End date *(dd MMM yyyy)*	5 OCT 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤

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

US3522269

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **21 Feb 2021 21:06:14**

Generated On: 10 Jun 2021 07:58:05

Were any concomitant procedures performed?   Yes ●

                                                      No ○

If yes, please complete Concomitant Procedures form.

US3522269

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4)   **25 Mar 2021 17:17:27**

Generated On: 10 Jun 2021 07:58:05

Procedure/Surgery date (*dd MMM yyyy*)	Procedure/Surgery	Indication	If indication is Other, specify
11 SEP 2020	ABDOMINA ULTRASOUND	Adverse Event	

Date of study discontinuation/completion *(dd MMM yyyy)*	13 OCT 2020

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

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

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

If main cause of death is Other, specify _____

Date of death *(dd MMM yyyy)* _____

Was autopsy performed?	
Yes	◯
No	◯
Unknown	◯

SAEID	USA-US131-2020-MRNA-1273-P30 1000005
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

SAEID	USA-US131-2020-MRNA-1273-P30 1000005
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/SEP/2020 07:53
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

SAEID	USA-US131-2020-MRNA-1273-P30 1000005
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/OCT/2020 12:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form (3)
Data signed: (b) (4) **21 Feb 2021 21:06:15**
Generated On: 10 Jun 2021 07:58:05

SAEID	USA-US131-2020-MRNA-1273-P30 1000005
Serious	Yes ● / No ○
Death	Yes ○ / No ●
Life threatening	Yes ○ / No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● / No ○
Persistent or significant disability or incapacity	Yes ○ / No ●
Congenital anomaly or birth defect	Yes ○ / No ●
Other medically important event	Yes ○ / No ●
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/OCT/2020 12:50
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

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) **21 Feb 2021 21:06:15**

Generated On: 10 Jun 2021 07:58:05

SAEID	USA-US131-2020-MRNA-1273-P30 1000005
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	25/NOV/2020 19:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) **21 Feb 2021 21:06:15**

Generated On: 10 Jun 2021 07:58:05

SAEID	USA-US131-2020-MRNA-1273-P30 1000005
Serious	Yes ● / No ○
Death	Yes ○ / No ●
Life threatening	Yes ○ / No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● / No ○
Persistent or significant disability or incapacity	Yes ○ / No ●
Congenital anomaly or birth defect	Yes ○ / No ●
Other medically important event	Yes ○ / No ●
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	15/DEC/2020 07:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3522269 (Prod: Henry Ford Health System)

US3522269

Form: Participant Creation

Generated On: 10 Jun 2021 07:58:05

Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered 'US3522269'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 12:14:11

US3522269
Form: Participant Creation
Generated On: 10 Jun 2021 07:58:05

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53

US3522269

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:58:05

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:24:52

US3522269

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:58:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered '21 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 12:14:12

Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:24:52

US3522269
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 07:58:05
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'SCRN'	System	21 Aug 2020 12:24:52

US3522269

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:05

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered (b) (6) 1976'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 12:14:13

US3522269

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:05

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered '44'	(b) (4), (b) (6)	21 Aug 2020 12:26:02

US3522269
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 07:58:05
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'YEARS'	System	21 Aug 2020 12:26:02

US3522269

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:05

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '44'	System	21 Aug 2020 12:26:29

US3522269

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:05

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:26:02

US3522269

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:05

Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	21 Aug 2020 12:26:02

US3522269

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:05

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered '1'	(b) (4), (b) (6)	21 Aug 2020 12:26:02

US3522269

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:05

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 12:26:02

US3522269

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:05

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:26:02

US3522269

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:05

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:26:02

US3522269

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:05

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:26:02

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:26:02

US3522269

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:05

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:26:02

US3522269

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:05

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:26:02

US3522269

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:05

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:26:02

US3522269

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:05

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:26:29

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'Aug 2020'	System	21 Aug 2020 12:26:29

FDA-CBER-2022-1614-0829129

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '2020'	System	21 Aug 2020 12:26:29

US3522269

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:05

Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered 'Amendment 2 (2)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	04 Sep 2020 15:13:29
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	21 Aug 2020 12:26:29

US3522269
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 07:58:05

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 12:26:29

US3522269

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:05

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:26:29

US3522269

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:05

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:26:29

Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 07:58:05

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:26:29

If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 12:14:12

US3522269

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:05

Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '1'	System	21 Aug 2020 12:26:34

US3522269

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 07:58:05

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 12:26:34

US3522269

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 07:58:05

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:26:40

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:05

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:32:57

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:32:57

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered '08:26'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:32:57

US3522269
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:58:05

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '21 Aug 2020 08:26'	System	21 Aug 2020 12:32:57

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:05

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered '62' in	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:32:57
DataPoint set to visible.	System	21 Aug 2020 12:26:34

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:05

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered '120.8' lb reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:57:26
User entered '120.8' kg	(b) (4), (b) (6)	21 Aug 2020 12:32:57
DataPoint set to visible.	System	21 Aug 2020 12:26:34

US3522269
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:58:05

BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '22.14081'	System	24 Sep 2020 15:57:26
Amendment Manager: User entered '48.70977'	System	17 Sep 2020 00:17:35
User closed query 'BMI $\geq$ 40 kg/m2 yet participant is not recorded as at risk. Please review and provide, reconcile, or clarification.' (Site from System).	(b) (4), (b) (6)	25 Aug 2020 15:34:41
Query 'BMI $\geq$ 40 kg/m2 yet participant is not recorded as at risk. Please review and provide, reconcile, or clarification.' answered with 'wrong cohort' (Site from System).	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 15:34:12
User opened query 'BMI $\geq$ 40 kg/m2 yet participant is not recorded as at risk. Please review and provide, reconcile, or clarification.' (Site from System).	System	21 Aug 2020 12:32:57
User entered '48.7'	System	21 Aug 2020 12:32:57
DataPoint set to visible.	System	21 Aug 2020 12:26:34

FDA-CBER-2022-1614-0829146

US3522269
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:58:05

BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'kg/m2'	System	21 Aug 2020 12:32:57
DataPoint set to visible.	System	21 Aug 2020 12:26:34

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:05

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Sharon Mathys (b) (4)	25 Aug 2020 15:34:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:00:31
User entered '97.7' F	(b) (4), (b) (6)	21 Aug 2020 12:32:57

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:05

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:00:31
User entered 'Other (Other)'	(b) (4), (b) (6)	21 Aug 2020 12:32:57

US3522269
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:58:05
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 15:34:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:00:31
User entered 'temporal'	(b) (4), (b) (6)	21 Aug 2020 12:32:57

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:00:31
User entered '81'	(b) (4), (b) (6)	21 Aug 2020 12:32:57

FDA-CBER-2022-1614-0829151

US3522269
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:58:05
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'bpm'	System	21 Aug 2020 12:32:57

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:00:31
User entered '15'	(b) (4), (b) (6)	21 Aug 2020 12:32:57

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'breaths/min'	System	21 Aug 2020 12:32:57

FDA-CBER-2022-1614-0829154

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:05

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:00:31
User entered '120'	(b) (4), (b) (6)	21 Aug 2020 12:32:57

Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:58:05
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'mmHg'	System	21 Aug 2020 12:32:57

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:00:31
User entered '80'	(b) (4), (b) (6)	21 Aug 2020 12:32:57

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'mmHg'	System	21 Aug 2020 12:32:57

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53

US3522269
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:58:05
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53

Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 07:58:05

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:33:06

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
	(b) (4)	
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 12:33:06

US3522269

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:58:05

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:33:57

US3522269

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:58:05

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User closed query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	25 Aug 2020 15:33:03
User opened query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	21 Aug 2020 12:33:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 12:33:57

US3522269

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:58:05

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:33:57

US3522269

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:58:05

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:33:57

US3522269

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:58:05

If Surgically sterile, date of surgery *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:33:57

US3522269

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:58:05

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:33:57

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:58:05

If Post-menopausal, date of last menstruation *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 15:33:03
User entered '7 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 12:33:57

US3522269

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:58:05

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:33:57

US3522269

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:58:05

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:39:39

US3522269

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:58:05

Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:39:39

US3522269

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:58:05

Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:39:39

US3522269
Folder: Screening
Form: Pregnancy Test
Generated On: 10 Jun 2021 07:58:05
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:39:39

US3522269

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:58:05

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:39:39

US3522269

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:58:05

Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 15:32:36
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 12:39:39

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 15:32:36
User entered '08:40' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 12:41:51
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:39:39

US3522269

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:58:05

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	25 Aug 2020 15:32:36
User entered '21 Aug 2020 08:40'	System	21 Aug 2020 12:41:51
User entered empty.	System	21 Aug 2020 12:39:39

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:05

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:40:26

Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 07:58:05

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:40:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:05

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)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:40:26

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:05

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)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:05

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:05

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)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:05

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)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:40:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:05

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)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:40:26

Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 07:58:05

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)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:05

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)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:05

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)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:40:26

US3522269
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 07:58:05
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:05

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:40:26

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered '1'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:05

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:05

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)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:05

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)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:05

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)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:40:26

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 12:40:26

US3522269
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 07:58:05
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:40:26

US3522269

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:58:05

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:40:44

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 12:40:44

FDA-CBER-2022-1614-0829201

US3522269

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Aug 2020 12:40:44

US3522269

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:58:05

Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'VISIT1'	System	21 Aug 2020 12:40:44

Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered '21 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 12:14:14

US3522269

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:05

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered '106826'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 12:14:14

US3522269

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:05

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 12:14:14

US3522269

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:05

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)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:41:00

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:05

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)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:41:00

US3522269

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User closed query 'Severe obesity is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	24 Sep 2020 15:57:51
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:57:51
User opened query 'Severe obesity is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	25 Aug 2020 15:33:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 15:33:42
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:41:00

US3522269

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:05

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:41:00

US3522269

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:05

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:41:00

US3522269

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:05

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:57:51
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:37:50
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:55:08

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:02:25
User entered '62' in	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:03:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:02:25
User entered '120.8' lb	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:02:25
User entered '62' in	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:03:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:02:25
User entered '120.8' lb	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:05

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:05

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:05

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered '08:26'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:05

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '21 Aug 2020 08:26'	System	21 Aug 2020 12:43:13

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered '97.7' F	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:05

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:05

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:05

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered '81'	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:05

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'bpm'	System	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:05

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered '15'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:43:13

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'breaths/min'	System	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:05

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered '120'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:05

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'mmHg'	System	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:05

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered '80'	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'mmHg'	System	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:02:25
User entered '62' in	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:03:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:02:25
User entered '120.8' lb	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:05

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:05

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 14:06:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 14:06:50
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:06:50
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 12:43:13
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:05

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:06:50
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered '10:05' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:06:50
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:05

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '21 Aug 2020 10:05'	System	21 Aug 2020 14:06:50
User entered empty.	System	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:05

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 14:07:04
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:07:04
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 14:06:50
User entered '98.1' (non-conformant).	(b) (4), (b) (6)	21 Aug 2020 14:06:50
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:43:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:05

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:06:50
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:05

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered 'Temporal' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:06:50
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:05

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered '76' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:06:50
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:43:13

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'bpm'	System	21 Aug 2020 14:06:50
User entered empty.	System	21 Aug 2020 12:43:13

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered '15' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:06:50
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:43:13

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:05

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'breaths/min'	System	21 Aug 2020 14:06:50
User entered empty.	System	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:05

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered '106' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:06:50
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:43:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:05

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'mmHg'	System	21 Aug 2020 14:06:50
User entered empty.	System	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:05

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered '78' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:06:50
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:43:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'mmHg'	System	21 Aug 2020 14:06:50
User entered empty.	System	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:05

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	04 Sep 2020 15:12:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 12:43:26

US3522269

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:05

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	04 Sep 2020 15:12:42
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 12:43:26

US3522269
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 10 Jun 2021 07:58:05

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User closed query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please consider to mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 16:41:16
Query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please consider to mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank. Thank you.' answered with 'done' (Site from DM).	Tyler Prentiss (b) (4) (b) (4)	01 Sep 2020 12:28:54
User entered 'No (N)' reason for change: Data Entry Error	Tyler Prentiss (b) (4) (b) (4)	01 Sep 2020 12:28:51
User opened query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please consider to mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 07:07:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 12:43:44

Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered empty; reason for change Data Entry Error	Tyler Prentiss (b) (4) (b) (4)	01 Sep 2020 12:28:51
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 12:43:44

US3522269

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:58:05

Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered empty; reason for change Data Entry Error	Tyler Prentiss (b) (4) (b) (4)	01 Sep 2020 12:28:51
User entered 'Urine (URINE)'	(b) (4), (b) (6)	21 Aug 2020 12:43:44

US3522269
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 10 Jun 2021 07:58:05
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered empty; reason for change Data Entry Error	Tyler Prentiss (b) (4) (b) (4)	01 Sep 2020 12:28:51
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	21 Aug 2020 12:43:44

US3522269

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:58:05

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:43:44

US3522269

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:58:05

Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered empty; reason for change Data Entry Error	Tyler Prentiss (b) (4) (b) (4)	01 Sep 2020 12:28:51
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 12:43:44

US3522269

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:58:05

Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered empty; reason for change Data Entry Error	Tyler Prentiss (b) (4) (b) (4)	01 Sep 2020 12:28:51
User entered '08:40'	(b) (4), (b) (6)	21 Aug 2020 12:43:44

US3522269

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:58:05

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	01 Sep 2020 12:28:51
User entered '21 Aug 2020 08:40'	System	21 Aug 2020 12:43:44

US3522269

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:05

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 13:26:24

US3522269
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 07:58:05
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:26:24

US3522269

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:05

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)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:26:24

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 13:26:24

FDA-CBER-2022-1614-0829264

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:26:24

FDA-CBER-2022-1614-0829265

US3522269

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered '09:35'	(b) (4), (b) (6)	21 Aug 2020 13:26:24

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '21 Aug 2020 09:35'	System	21 Aug 2020 13:26:24

US3522269

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:05

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:26:24

US3522269
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 07:58:05
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'ONCE'	System	21 Aug 2020 13:26:24

US3522269
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 07:58:05
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 13:26:24

US3522269

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:05

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:17:30

US3522269

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:05

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:17:30

US3522269

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered '09:13'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:17:30

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '21 Aug 2020 09:13'	System	21 Aug 2020 13:17:30

US3522269

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:58:05

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:17:46

US3522269

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:58:05

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Aug 2020 13:17:46

US3522269

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:58:05

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:17:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered '09:15'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:17:46

US3522269

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:58:05

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '21 Aug 2020 09:15'	System	21 Aug 2020 13:17:46

US3522269

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:05

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Aug 2020 13:17:46

US3522269

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:05

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:17:46

US3522269

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:17:46

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:05

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	21 Aug 2020 13:17:46

US3522269

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:58:05

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:45:15

US3522269

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:58:05

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '1'	System	21 Aug 2020 12:45:15

US3522269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 07:58:05
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T10:00:41', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'b2bdd2d2-1830-4981-8057-28b071b45a41'	System	21 Aug 2020 14:06:29
User entered 'Yes (Y)'	System	21 Aug 2020 14:06:29

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T10:06:10', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'b2bdd2d2-1830-4981-8057-28b071b45a41'	System	21 Aug 2020 14:06:29
User entered '98.1'	System	21 Aug 2020 14:06:29

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T10:06:16', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'b2bdd2d2-1830-4981-8057-28b071b45a41'	System	21 Aug 2020 14:06:29
User entered 'No (N)'	System	21 Aug 2020 14:06:29

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T10:06:24', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'b2bdd2d2-1830-4981-8057-28b071b45a41'	System	21 Aug 2020 14:06:29
User entered '21 Aug 2020 10:06'	System	21 Aug 2020 14:06:29

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '21 Aug 2020 09:55'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '21 Aug 2020 12:25'	System	21 Aug 2020 13:26:24

US3522269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 07:58:05
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:42:51', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '297e4493-ce85-4c79-8261-ee2f84134363'	System	21 Aug 2020 20:44:28
User entered 'Yes (Y)'	System	21 Aug 2020 20:44:28

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:44:14', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '297e4493-ce85-4c79-8261-ee2f84134363'	System	21 Aug 2020 20:44:28
User entered '98.8'	System	21 Aug 2020 20:44:28

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:44:18', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '297e4493-ce85-4c79-8261-ee2f84134363'	System	21 Aug 2020 20:44:28
User entered 'No (N)'	System	21 Aug 2020 20:44:28

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:44:25', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '297e4493-ce85-4c79-8261-ee2f84134363'	System	21 Aug 2020 20:44:28
User entered '21 Aug 2020 16:44'	System	21 Aug 2020 20:44:28

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '21 Aug 2020 13:20'	System	21 Aug 2020 13:26:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

FDA-CBER-2022-1614-0829299

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 2'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:03:53', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '35ceb7db-c487-4b24-a985-bd215b1c20c3'	System	22 Aug 2020 20:04:41
User entered 'Yes (Y)'	System	22 Aug 2020 20:04:41

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:05

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:04:28', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '35ceb7db-c487-4b24-a985-bd215b1c20c3'	System	22 Aug 2020 20:04:41
User entered '97.7'	System	22 Aug 2020 20:04:41

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:04:33', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '35ceb7db-c487-4b24-a985-bd215b1c20c3'	System	22 Aug 2020 20:04:41
User entered 'No (N)'	System	22 Aug 2020 20:04:41

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:04:39', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '35ceb7db-c487-4b24-a985-bd215b1c20c3'	System	22 Aug 2020 20:04:41
User entered '22 Aug 2020 16:04'	System	22 Aug 2020 20:04:41

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 3'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:04:16', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '637f6cad-2064-4925-b389-e22a48befd02'	System	23 Aug 2020 16:04:39
User entered 'Yes (Y)'	System	23 Aug 2020 16:04:39

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:05

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:04:26', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '637f6cad-2064-4925-b389-e22a48befd02'	System	23 Aug 2020 16:04:39
User entered '98.8'	System	23 Aug 2020 16:04:39

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:04:29', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '637f6cad-2064-4925-b389-e22a48befd02'	System	23 Aug 2020 16:04:39
User entered 'No (N)'	System	23 Aug 2020 16:04:39

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:04:34', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '637f6cad-2064-4925-b389-e22a48befd02'	System	23 Aug 2020 16:04:39
User entered '23 Aug 2020 12:04'	System	23 Aug 2020 16:04:39

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

FDA-CBER-2022-1614-0829312

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 4'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:40:11', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '50fb3630-1c70-4725-9aad-c21b677e7e6f'	System	24 Aug 2020 17:40:35
User entered 'Yes (Y)'	System	24 Aug 2020 17:40:35

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:05

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:40:22', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '50fb3630-1c70-4725-9aad-c21b677e7e6f'	System	24 Aug 2020 17:40:35
User entered '98.2'	System	24 Aug 2020 17:40:35

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:40:27', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '50fb3630-1c70-4725-9aad-c21b677e7e6f'	System	24 Aug 2020 17:40:35
User entered 'No (N)'	System	24 Aug 2020 17:40:35

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:40:32', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '50fb3630-1c70-4725-9aad-c21b677e7e6f'	System	24 Aug 2020 17:40:35
User entered '24 Aug 2020 13:40'	System	24 Aug 2020 17:40:35

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 5'	System	21 Aug 2020 13:26:24

US3522269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 07:58:05
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:04:25', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '4b924c15-1714-4ad8-9b3f-8e36d39f8af6'	System	25 Aug 2020 16:04:50
User entered 'Yes (Y)'	System	25 Aug 2020 16:04:50

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:05

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:04:34', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '4b924c15-1714-4ad8-9b3f-8e36d39f8af6'	System	25 Aug 2020 16:04:50
User entered '98.3'	System	25 Aug 2020 16:04:50

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:04:38', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '4b924c15-1714-4ad8-9b3f-8e36d39f8af6'	System	25 Aug 2020 16:04:50
User entered 'No (N)'	System	25 Aug 2020 16:04:50

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:04:41', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '4b924c15-1714-4ad8-9b3f-8e36d39f8af6'	System	25 Aug 2020 16:04:50
User entered '25 Aug 2020 12:04'	System	25 Aug 2020 16:04:50

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 07:58:05
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 6'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:08:21', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'e204e630-7f8e-41eb-86a0-124a92f3a0e3'	System	26 Aug 2020 17:08:55
User entered 'Yes (Y)'	System	26 Aug 2020 17:08:55

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:05

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:08:35', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'e204e630-7f8e-41eb-86a0-124a92f3a0e3'	System	26 Aug 2020 17:08:55
User entered '98.4'	System	26 Aug 2020 17:08:55

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:08:41', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'e204e630-7f8e-41eb-86a0-124a92f3a0e3'	System	26 Aug 2020 17:08:55
User entered 'No (N)'	System	26 Aug 2020 17:08:55

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:08:46', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'e204e630-7f8e-41eb-86a0-124a92f3a0e3'	System	26 Aug 2020 17:08:55
User entered '26 Aug 2020 13:08'	System	26 Aug 2020 17:08:55

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 07:58:05
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 7'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:04:47', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ffab3c11-7a93-42f2-8e15-1cc57dcc99dd'	System	27 Aug 2020 17:05:20
User entered 'Yes (Y)'	System	27 Aug 2020 17:05:20

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:05

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:05:01', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ffab3c11-7a93-42f2-8e15-1cc57dcc99dd'	System	27 Aug 2020 17:05:20
User entered '98.5'	System	27 Aug 2020 17:05:20

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:05:07', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ffab3c11-7a93-42f2-8e15-1cc57dcc99dd'	System	27 Aug 2020 17:05:20
User entered 'No (N)'	System	27 Aug 2020 17:05:20

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:05:16', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ffab3c11-7a93-42f2-8e15-1cc57dcc99dd'	System	27 Aug 2020 17:05:20
User entered '27 Aug 2020 13:05'	System	27 Aug 2020 17:05:20

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

FDA-CBER-2022-1614-0829340

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 07:58:05
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T11:35:14', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd92c5b93-6a4a-4211-abee-85ea41713321'	System	21 Aug 2020 15:35:57
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 15:35:57

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T11:35:35', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd92c5b93-6a4a-4211-abee-85ea41713321'	System	21 Aug 2020 15:35:57
User entered 'No (N)'	System	21 Aug 2020 15:35:57

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T11:35:39', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd92c5b93-6a4a-4211-abee-85ea41713321'	System	21 Aug 2020 15:35:57
User entered 'No (N)'	System	21 Aug 2020 15:35:57

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T11:35:45', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd92c5b93-6a4a-4211-abee-85ea41713321'	System	21 Aug 2020 15:35:57
User entered 'None (1)'	System	21 Aug 2020 15:35:57

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T11:35:53', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd92c5b93-6a4a-4211-abee-85ea41713321'	System	21 Aug 2020 15:35:57
User entered '21 Aug 2020 11:35'	System	21 Aug 2020 15:35:57

US3522269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 07:58:05
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '21 Aug 2020 09:55'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '21 Aug 2020 12:25'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 13:26:24

US3522269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:44:30', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '35cc7b71-052e-4676-b9d9-bc55d5c98ca5'	System	21 Aug 2020 20:44:49
User entered 'None (1)'	System	21 Aug 2020 20:44:49

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:44:34', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '35cc7b71-052e-4676-b9d9-bc55d5c98ca5'	System	21 Aug 2020 20:44:49
User entered 'No (N)'	System	21 Aug 2020 20:44:49

FDA-CBER-2022-1614-0829352

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:44:37', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '35cc7b71-052e-4676-b9d9-bc55d5c98ca5'	System	21 Aug 2020 20:44:49
User entered 'No (N)'	System	21 Aug 2020 20:44:49

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:44:40', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '35cc7b71-052e-4676-b9d9-bc55d5c98ca5'	System	21 Aug 2020 20:44:49
User entered 'None (1)'	System	21 Aug 2020 20:44:49

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:44:44', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '35cc7b71-052e-4676-b9d9-bc55d5c98ca5'	System	21 Aug 2020 20:44:49
User entered '21 Aug 2020 16:44'	System	21 Aug 2020 20:44:49

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '21 Aug 2020 13:20'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 2'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:04:45', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'cb17d1e8-3121-4f4b-b650-7cfe2db01bca'	System	22 Aug 2020 20:04:58
User entered 'None (1)'	System	22 Aug 2020 20:04:58

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:04:48', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'cb17d1e8-3121-4f4b-b650-7cfe2db01bca'	System	22 Aug 2020 20:04:58
User entered 'No (N)'	System	22 Aug 2020 20:04:58

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:04:51', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'cb17d1e8-3121-4f4b-b650-7cfe2db01bca'	System	22 Aug 2020 20:04:58
User entered 'No (N)'	System	22 Aug 2020 20:04:58

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:04:54', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'cb17d1e8-3121-4f4b-b650-7cfe2db01bca'	System	22 Aug 2020 20:04:58
User entered 'None (1)'	System	22 Aug 2020 20:04:58

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:04:57', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'cb17d1e8-3121-4f4b-b650-7cfe2db01bca'	System	22 Aug 2020 20:04:58
User entered '22 Aug 2020 16:04'	System	22 Aug 2020 20:04:58

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

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US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 3'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:04:39', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3ad6d9dc-b2c3-47a7-8c45-8e54cf95e60f'	System	23 Aug 2020 16:05:01
User entered 'None (1)'	System	23 Aug 2020 16:05:01

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:04:46', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3ad6d9dc-b2c3-47a7-8c45-8e54cf95e60f'	System	23 Aug 2020 16:05:01
User entered 'No (N)'	System	23 Aug 2020 16:05:01

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:04:50', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3ad6d9dc-b2c3-47a7-8c45-8e54cf95e60f'	System	23 Aug 2020 16:05:01
User entered 'No (N)'	System	23 Aug 2020 16:05:01

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:04:53', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3ad6d9dc-b2c3-47a7-8c45-8e54cf95e60f'	System	23 Aug 2020 16:05:01
User entered 'None (1)'	System	23 Aug 2020 16:05:01

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:04:56', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3ad6d9dc-b2c3-47a7-8c45-8e54cf95e60f'	System	23 Aug 2020 16:05:01
User entered '23 Aug 2020 12:04'	System	23 Aug 2020 16:05:01

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

FDA-CBER-2022-1614-0829373

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 4'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:40:38', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c6d9ec94-6301-4139-a2da-5788149d605e'	System	24 Aug 2020 17:41:08
User entered 'None (1)'	System	24 Aug 2020 17:41:08

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:40:41', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c6d9ec94-6301-4139-a2da-5788149d605e'	System	24 Aug 2020 17:41:08
User entered 'No (N)'	System	24 Aug 2020 17:41:08

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:40:44', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c6d9ec94-6301-4139-a2da-5788149d605e'	System	24 Aug 2020 17:41:08
User entered 'No (N)'	System	24 Aug 2020 17:41:08

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:40:48', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c6d9ec94-6301-4139-a2da-5788149d605e'	System	24 Aug 2020 17:41:08
User entered 'None (1)'	System	24 Aug 2020 17:41:08

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:40:52', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c6d9ec94-6301-4139-a2da-5788149d605e'	System	24 Aug 2020 17:41:08
User entered '24 Aug 2020 13:40'	System	24 Aug 2020 17:41:08

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 07:58:05
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 5'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:04:59', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd109f95a-f5a0-4da4-8381-51e30a9e83db'	System	25 Aug 2020 16:06:36
User entered 'Does not interfere with activity (2)'	System	25 Aug 2020 16:06:36

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:05:03', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd109f95a-f5a0-4da4-8381-51e30a9e83db'	System	25 Aug 2020 16:06:36
User entered 'Yes (Y)'	System	25 Aug 2020 16:06:36

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:05

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:06:06', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd109f95a-f5a0-4da4-8381-51e30a9e83db'	System	25 Aug 2020 16:06:36
User entered '2'	System	25 Aug 2020 16:06:36

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:06:11', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd109f95a-f5a0-4da4-8381-51e30a9e83db'	System	25 Aug 2020 16:06:36
User entered 'Yes (Y)'	System	25 Aug 2020 16:06:36

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:05

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:06:23', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd109f95a-f5a0-4da4-8381-51e30a9e83db'	System	25 Aug 2020 16:06:36
User entered '5'	System	25 Aug 2020 16:06:36

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:06:28', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd109f95a-f5a0-4da4-8381-51e30a9e83db'	System	25 Aug 2020 16:06:36
User entered 'None (1)'	System	25 Aug 2020 16:06:36

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:06:31', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd109f95a-f5a0-4da4-8381-51e30a9e83db'	System	25 Aug 2020 16:06:36
User entered '25 Aug 2020 12:06'	System	25 Aug 2020 16:06:36

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 6'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:08:57', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0a72c48f-0206-46a4-8fed-a4f434c9fef0'	System	26 Aug 2020 17:10:28
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:09:04', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0a72c48f-0206-46a4-8fed-a4f434c9fef0'	System	26 Aug 2020 17:10:28
User entered 'Yes (Y)'	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:05

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:09:49', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0a72c48f-0206-46a4-8fed-a4f434c9fef0'	System	26 Aug 2020 17:10:28
User entered '3'	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:09:55', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0a72c48f-0206-46a4-8fed-a4f434c9fef0'	System	26 Aug 2020 17:10:28
User entered 'Yes (Y)'	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:05

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:10:09', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0a72c48f-0206-46a4-8fed-a4f434c9fef0'	System	26 Aug 2020 17:10:28
User entered '3'	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:10:16', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0a72c48f-0206-46a4-8fed-a4f434c9fef0'	System	26 Aug 2020 17:10:28
User entered 'None (1)'	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:10:21', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0a72c48f-0206-46a4-8fed-a4f434c9fef0'	System	26 Aug 2020 17:10:28
User entered '26 Aug 2020 13:10'	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 07:58:05
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 7'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:05:26', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff9c6954-5027-4bf0-8b40-a54101f013d1'	System	27 Aug 2020 17:06:17
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 17:06:17

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:05:49', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff9c6954-5027-4bf0-8b40-a54101f013d1'	System	27 Aug 2020 17:06:17
User entered 'No (N)'	System	27 Aug 2020 17:06:17

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:05:55', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff9c6954-5027-4bf0-8b40-a54101f013d1'	System	27 Aug 2020 17:06:17
User entered 'No (N)'	System	27 Aug 2020 17:06:17

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:06:01', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff9c6954-5027-4bf0-8b40-a54101f013d1'	System	27 Aug 2020 17:06:17
User entered 'None (1)'	System	27 Aug 2020 17:06:17

US3522269
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 07:58:05
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:06:09', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff9c6954-5027-4bf0-8b40-a54101f013d1'	System	27 Aug 2020 17:06:17
User entered '27 Aug 2020 13:06'	System	27 Aug 2020 17:06:17

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:58:05
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T11:36:14', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ebf13b5e-f600-4029-b4b0-99777cc1e234'	System	21 Aug 2020 15:36:46
User entered 'No interference with activity (1)'	System	21 Aug 2020 15:36:46

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:58:05
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T11:36:19', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ebf13b5e-f600-4029-b4b0-99777cc1e234'	System	21 Aug 2020 15:36:46
User entered 'None (0)'	System	21 Aug 2020 15:36:46

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:58:05
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T11:36:24', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ebf13b5e-f600-4029-b4b0-99777cc1e234'	System	21 Aug 2020 15:36:46
User entered 'None (0)'	System	21 Aug 2020 15:36:46

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T11:36:28', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ebf13b5e-f600-4029-b4b0-99777cc1e234'	System	21 Aug 2020 15:36:46
User entered 'None (0)'	System	21 Aug 2020 15:36:46

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:58:05
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T11:36:31', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ebf13b5e-f600-4029-b4b0-99777cc1e234'	System	21 Aug 2020 15:36:46
User entered 'None (0)'	System	21 Aug 2020 15:36:46

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:58:05
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T11:36:34', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ebf13b5e-f600-4029-b4b0-99777cc1e234'	System	21 Aug 2020 15:36:46
User entered 'None (0)'	System	21 Aug 2020 15:36:46

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T11:36:40', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ebf13b5e-f600-4029-b4b0-99777cc1e234'	System	21 Aug 2020 15:36:46
User entered 'No (N)'	System	21 Aug 2020 15:36:46

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T11:36:43', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ebf13b5e-f600-4029-b4b0-99777cc1e234'	System	21 Aug 2020 15:36:46
User entered '21 Aug 2020 11:36'	System	21 Aug 2020 15:36:46

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '21 Aug 2020 09:55'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '21 Aug 2020 12:25'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:44:49', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '1614234f-b771-4219-a1c4-6225a6110261'	System	21 Aug 2020 20:45:19
User entered 'None (0)'	System	21 Aug 2020 20:45:19

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:58:05
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:44:52', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '1614234f-b771-4219-a1c4-6225a6110261'	System	21 Aug 2020 20:45:19
User entered 'No interference with activity (1)'	System	21 Aug 2020 20:45:19

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:44:56', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '1614234f-b771-4219-a1c4-6225a6110261'	System	21 Aug 2020 20:45:19
User entered 'None (0)'	System	21 Aug 2020 20:45:19

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:44:59', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '1614234f-b771-4219-a1c4-6225a6110261'	System	21 Aug 2020 20:45:19
User entered 'None (0)'	System	21 Aug 2020 20:45:19

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:45:02', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '1614234f-b771-4219-a1c4-6225a6110261'	System	21 Aug 2020 20:45:19
User entered 'None (0)'	System	21 Aug 2020 20:45:19

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:45:04', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '1614234f-b771-4219-a1c4-6225a6110261'	System	21 Aug 2020 20:45:19
User entered 'None (0)'	System	21 Aug 2020 20:45:19

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:45:11', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '1614234f-b771-4219-a1c4-6225a6110261'	System	21 Aug 2020 20:45:19
User entered 'No (N)'	System	21 Aug 2020 20:45:19

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:45:14', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '1614234f-b771-4219-a1c4-6225a6110261'	System	21 Aug 2020 20:45:19
User entered '21 Aug 2020 16:45'	System	21 Aug 2020 20:45:19

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '21 Aug 2020 13:20'	System	21 Aug 2020 13:26:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

FDA-CBER-2022-1614-0829431

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 2'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:05:03', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd01732d2-27d9-4e4a-b5b9-09b837f38a6e'	System	22 Aug 2020 20:05:26
User entered 'No interference with activity (1)'	System	22 Aug 2020 20:05:26

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:58:05
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:05:06', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd01732d2-27d9-4e4a-b5b9-09b837f38a6e'	System	22 Aug 2020 20:05:26
User entered 'No interference with activity (1)'	System	22 Aug 2020 20:05:26

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:05:09', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd01732d2-27d9-4e4a-b5b9-09b837f38a6e'	System	22 Aug 2020 20:05:26
User entered 'None (0)'	System	22 Aug 2020 20:05:26

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:05:11', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd01732d2-27d9-4e4a-b5b9-09b837f38a6e'	System	22 Aug 2020 20:05:26
User entered 'None (0)'	System	22 Aug 2020 20:05:26

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:58:05
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:05:14', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd01732d2-27d9-4e4a-b5b9-09b837f38a6e'	System	22 Aug 2020 20:05:26
User entered 'None (0)'	System	22 Aug 2020 20:05:26

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:58:05
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:05:16', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd01732d2-27d9-4e4a-b5b9-09b837f38a6e'	System	22 Aug 2020 20:05:26
User entered 'None (0)'	System	22 Aug 2020 20:05:26

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:05:20', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd01732d2-27d9-4e4a-b5b9-09b837f38a6e'	System	22 Aug 2020 20:05:26
User entered 'No (N)'	System	22 Aug 2020 20:05:26

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:05

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:05:23', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd01732d2-27d9-4e4a-b5b9-09b837f38a6e'	System	22 Aug 2020 20:05:26
User entered '22 Aug 2020 16:05'	System	22 Aug 2020 20:05:26

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 3'	System	21 Aug 2020 13:26:24

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:58:05
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:05:01', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '4d74408b-e48a-46c4-83aa-0bec390ad9c9'	System	23 Aug 2020 16:05:27
User entered 'None (0)'	System	23 Aug 2020 16:05:27

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:58:05
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:05:03', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '4d74408b-e48a-46c4-83aa-0bec390ad9c9'	System	23 Aug 2020 16:05:27
User entered 'None (0)'	System	23 Aug 2020 16:05:27

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:05:10', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '4d74408b-e48a-46c4-83aa-0bec390ad9c9'	System	23 Aug 2020 16:05:27
User entered 'None (0)'	System	23 Aug 2020 16:05:27

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:05:13', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '4d74408b-e48a-46c4-83aa-0bec390ad9c9'	System	23 Aug 2020 16:05:27
User entered 'None (0)'	System	23 Aug 2020 16:05:27

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:05:15', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '4d74408b-e48a-46c4-83aa-0bec390ad9c9'	System	23 Aug 2020 16:05:27
User entered 'None (0)'	System	23 Aug 2020 16:05:27

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:58:05
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:05:17', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '4d74408b-e48a-46c4-83aa-0bec390ad9c9'	System	23 Aug 2020 16:05:27
User entered 'None (0)'	System	23 Aug 2020 16:05:27

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:05:20', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '4d74408b-e48a-46c4-83aa-0bec390ad9c9'	System	23 Aug 2020 16:05:27
User entered 'No (N)'	System	23 Aug 2020 16:05:27

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:05

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:05:22', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '4d74408b-e48a-46c4-83aa-0bec390ad9c9'	System	23 Aug 2020 16:05:27
User entered '23 Aug 2020 12:05'	System	23 Aug 2020 16:05:27

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:58:05
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 4'	System	21 Aug 2020 13:26:24

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:58:05
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:40:58', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0d410726-db4a-4906-8e0c-84a0f2931af8'	System	24 Aug 2020 17:41:25
User entered 'None (0)'	System	24 Aug 2020 17:41:25

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:58:05
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:41:01', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0d410726-db4a-4906-8e0c-84a0f2931af8'	System	24 Aug 2020 17:41:25
User entered 'None (0)'	System	24 Aug 2020 17:41:25

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:58:05
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:41:04', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0d410726-db4a-4906-8e0c-84a0f2931af8'	System	24 Aug 2020 17:41:25
User entered 'None (0)'	System	24 Aug 2020 17:41:25

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:41:06', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0d410726-db4a-4906-8e0c-84a0f2931af8'	System	24 Aug 2020 17:41:25
User entered 'None (0)'	System	24 Aug 2020 17:41:25

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:58:05
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:41:10', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0d410726-db4a-4906-8e0c-84a0f2931af8'	System	24 Aug 2020 17:41:25
User entered 'None (0)'	System	24 Aug 2020 17:41:25

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:41:13', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0d410726-db4a-4906-8e0c-84a0f2931af8'	System	24 Aug 2020 17:41:25
User entered 'None (0)'	System	24 Aug 2020 17:41:25

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:41:18', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0d410726-db4a-4906-8e0c-84a0f2931af8'	System	24 Aug 2020 17:41:25
User entered 'No (N)'	System	24 Aug 2020 17:41:25

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:05

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:41:22', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0d410726-db4a-4906-8e0c-84a0f2931af8'	System	24 Aug 2020 17:41:25
User entered '24 Aug 2020 13:41'	System	24 Aug 2020 17:41:25

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:58:05
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 5'	System	21 Aug 2020 13:26:24

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:58:05
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:06:39', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '96e3f228-9c09-4a9c-b605-3ad3134b5683'	System	25 Aug 2020 16:07:06
User entered 'None (0)'	System	25 Aug 2020 16:07:06

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:58:05
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:06:42', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '96e3f228-9c09-4a9c-b605-3ad3134b5683'	System	25 Aug 2020 16:07:06
User entered 'None (0)'	System	25 Aug 2020 16:07:06

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:06:45', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '96e3f228-9c09-4a9c-b605-3ad3134b5683'	System	25 Aug 2020 16:07:06
User entered 'None (0)'	System	25 Aug 2020 16:07:06

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:06:48', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '96e3f228-9c09-4a9c-b605-3ad3134b5683'	System	25 Aug 2020 16:07:06
User entered 'None (0)'	System	25 Aug 2020 16:07:06

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:58:05
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:06:51', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '96e3f228-9c09-4a9c-b605-3ad3134b5683'	System	25 Aug 2020 16:07:06
User entered 'None (0)'	System	25 Aug 2020 16:07:06

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:58:05
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:06:54', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '96e3f228-9c09-4a9c-b605-3ad3134b5683'	System	25 Aug 2020 16:07:06
User entered 'None (0)'	System	25 Aug 2020 16:07:06

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:06:57', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '96e3f228-9c09-4a9c-b605-3ad3134b5683'	System	25 Aug 2020 16:07:06
User entered 'No (N)'	System	25 Aug 2020 16:07:06

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:05

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:07:00', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '96e3f228-9c09-4a9c-b605-3ad3134b5683'	System	25 Aug 2020 16:07:06
User entered '25 Aug 2020 12:07'	System	25 Aug 2020 16:07:06

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:58:05
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 6'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:10:31', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '70649d1a-50df-437d-abd7-a485ce84fd59'	System	26 Aug 2020 17:11:23
User entered 'No interference with activity (1)'	System	26 Aug 2020 17:11:23

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:58:05
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:10:38', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '70649d1a-50df-437d-abd7-a485ce84fd59'	System	26 Aug 2020 17:11:23
User entered 'None (0)'	System	26 Aug 2020 17:11:23

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:10:48', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '70649d1a-50df-437d-abd7-a485ce84fd59'	System	26 Aug 2020 17:11:23
User entered 'None (0)'	System	26 Aug 2020 17:11:23

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:10:54', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '70649d1a-50df-437d-abd7-a485ce84fd59'	System	26 Aug 2020 17:11:23
User entered 'None (0)'	System	26 Aug 2020 17:11:23

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:11:00', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '70649d1a-50df-437d-abd7-a485ce84fd59'	System	26 Aug 2020 17:11:23
User entered 'None (0)'	System	26 Aug 2020 17:11:23

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:11:05', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '70649d1a-50df-437d-abd7-a485ce84fd59'	System	26 Aug 2020 17:11:23
User entered 'None (0)'	System	26 Aug 2020 17:11:23

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:11:16', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '70649d1a-50df-437d-abd7-a485ce84fd59'	System	26 Aug 2020 17:11:23
User entered 'No (N)'	System	26 Aug 2020 17:11:23

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:05

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:11:20', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '70649d1a-50df-437d-abd7-a485ce84fd59'	System	26 Aug 2020 17:11:23
User entered '26 Aug 2020 13:11'	System	26 Aug 2020 17:11:23

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 7'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:06:20', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2d9a04f5-3003-42bf-8197-1caac000a017'	System	27 Aug 2020 17:06:56
User entered 'None (0)'	System	27 Aug 2020 17:06:56

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:58:05
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:06:25', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2d9a04f5-3003-42bf-8197-1caac000a017'	System	27 Aug 2020 17:06:56
User entered 'None (0)'	System	27 Aug 2020 17:06:56

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:58:05
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:06:30', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2d9a04f5-3003-42bf-8197-1caac000a017'	System	27 Aug 2020 17:06:56
User entered 'None (0)'	System	27 Aug 2020 17:06:56

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:06:34', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2d9a04f5-3003-42bf-8197-1caac000a017'	System	27 Aug 2020 17:06:56
User entered 'None (0)'	System	27 Aug 2020 17:06:56

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:58:05
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:06:39', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2d9a04f5-3003-42bf-8197-1caac000a017'	System	27 Aug 2020 17:06:56
User entered 'None (0)'	System	27 Aug 2020 17:06:56

US3522269
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:58:05
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:06:43', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2d9a04f5-3003-42bf-8197-1caac000a017'	System	27 Aug 2020 17:06:56
User entered 'None (0)'	System	27 Aug 2020 17:06:56

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:06:48', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2d9a04f5-3003-42bf-8197-1caac000a017'	System	27 Aug 2020 17:06:56
User entered 'No (N)'	System	27 Aug 2020 17:06:56

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:05

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:06:52', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2d9a04f5-3003-42bf-8197-1caac000a017'	System	27 Aug 2020 17:06:56
User entered '27 Aug 2020 13:06'	System	27 Aug 2020 17:06:56

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269
Folder: Diary Dose 1 (1)
Form: Injection Pain_Day(8)
Generated On: 10 Jun 2021 07:58:05
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	26 Aug 2020 17:10:28
User entered 'Day 8'	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 10 Jun 2021 07:58:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15

US3522269
Folder: Diary Dose 1 (1)
Form: Injection Pain_Day(8)
Generated On: 10 Jun 2021 07:58:05
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	27 Aug 2020 17:06:17
User entered 'Day 9'	System	27 Aug 2020 17:06:17

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 10 Jun 2021 07:58:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 17:06:17

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 17:06:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	26 Aug 2020 17:10:28
User entered 'Day 8'	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 07:58:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15

US3522269

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 07:58:05

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	27 Aug 2020 17:06:17
User entered 'Day 9'	System	27 Aug 2020 17:06:17

US3522269

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 07:58:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15

US3522269

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 07:58:05

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15

US3522269

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 17:06:17

US3522269

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 17:06:17

US3522269

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:05

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:07:36

US3522269

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:12
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 18:07:36

Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:58:05

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:12
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	28 Aug 2020 18:07:36

FDA-CBER-2022-1614-0829520

US3522269

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:05

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:12
User entered 'attempted to reach patient with no success. will attempt at later time.'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 18:07:36

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:12
User entered 'Yes (Y)'	Tyler Prentiss (b) (4) (b) (4)	04 Sep 2020 18:10:38

US3522269

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:05

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '1'	System	04 Sep 2020 18:10:38

US3522269

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:05

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:12
User entered 'Yes (Y)'	Tyler Prentiss (b) (4) (b) (4)	04 Sep 2020 18:12:58

US3522269

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:12
User entered '04 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	10 Nov 2020 17:53:44
User entered '4 Sep 2020'	Tyler Prentiss (b) (4) (b) (4)	04 Sep 2020 18:12:58

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:12
User entered 'Contact Not Made (CONTACT NOT MADE)'	Tyler Prentiss (b) (4) (b) (4)	04 Sep 2020 18:12:58

US3522269

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:05

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:12
User entered 'Contact not made; voicemail left'	Tyler Prentiss (b) (4) (b) (4)	04 Sep 2020 18:12:58

US3522269

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:05

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:12
User entered 'Yes (Y)'	Tyler Prentiss (b) (4) (b) (4)	04 Sep 2020 18:13:04

US3522269
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:58:05
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '1'	System	04 Sep 2020 18:13:04

US3522269

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:05

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:12
User entered 'Yes (Y)'	Alayna Wilder (b) (4) (b) (4)	11 Sep 2020 15:25:21

US3522269
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:58:05
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:12
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 05:56:09
User entered '16 Sep 2020' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	16 Sep 2020 21:53:02
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'multiple contact attempts; see audit history' (Site from System).	Yaman Ahmed (b) (4) (b) (4)	15 Sep 2020 21:15:28
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	15 Sep 2020 21:15:16
User entered '15 Sep 2020' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	15 Sep 2020 21:15:16
User entered '11 Sep 2020'	Alayna Wilder (b) (4) (b) (4)	11 Sep 2020 15:25:21

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:12
User entered 'Contact Not Made (CONTACT NOT MADE)'	Alayna Wilder (b) (4) (b) (4)	11 Sep 2020 15:25:21

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Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:05

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:12
User entered '1ST ATTEMPT 11 SEP 2020; 2ND ATTEMPT 15 SEP 2020; 3rd attempt 16 Sep 2020' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	16 Sep 2020 21:53:02
User entered '1st attempt 11 Sep 2020; 2nd attempt 15 Sep 2020' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	15 Sep 2020 21:15:16
User entered 'left vm'	Alayna Wilder (b) (4) (b) (4)	11 Sep 2020 15:25:21

US3522269

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:05

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 17:58:34

Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:58:05
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '1'	System	22 Sep 2020 17:58:34

Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 07:58:05

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 17:58:44

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
	(b) (4)	
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 17:58:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 17:58:44

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'VISIT2'	System	22 Sep 2020 17:58:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:05

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Sep 2020 17:59:50

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:05

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 17:59:50

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:05

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 17:59:50

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	29 Sep 2020 15:18:52
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	22 Sep 2020 18:50:24
User entered '13:47'	(b) (4), (b) (6)	22 Sep 2020 17:59:50

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '22 Sep 2020 13:47'	System	22 Sep 2020 17:59:50

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:05

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered '98.3' F	(b) (4), (b) (6)	22 Sep 2020 17:59:50

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered 'Other (Other)'	(b) (4), (b) (6)	22 Sep 2020 17:59:50

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:05

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered 'Temporal'	(b) (4), (b) (6)	22 Sep 2020 17:59:50

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:05

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered '86'	(b) (4), (b) (6)	22 Sep 2020 17:59:50

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'bpm'	System	22 Sep 2020 17:59:50

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Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered '14'	(b) (4), (b) (6)	22 Sep 2020 17:59:50

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'breaths/min'	System	22 Sep 2020 17:59:50

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered '108'	(b) (4), (b) (6)	22 Sep 2020 17:59:50

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'mmHg'	System	22 Sep 2020 17:59:50

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:05

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered '65'	(b) (4), (b) (6)	22 Sep 2020 17:59:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'mmHg'	System	22 Sep 2020 17:59:50

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:05

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Sep 2020 18:53:44

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 18:53:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:05

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:53:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered '14:45' reason for change: New Information	(b) (4), (b) (6)	15 Oct 2020 18:51:45
User entered '14:15'	(b) (4), (b) (6)	22 Sep 2020 18:53:44

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '22 Sep 2020 14:45'	System	15 Oct 2020 18:51:45
User entered '22 Sep 2020 14:15'	System	22 Sep 2020 18:53:44

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US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:05

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered '98.2' F	(b) (4), (b) (6)	22 Sep 2020 18:53:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:05

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:53:44

US3522269
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:58:05
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered 'TEMPORAL'	(b) (4), (b) (6)	22 Sep 2020 18:53:44

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered '84'	(b) (4), (b) (6)	22 Sep 2020 18:53:44

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'bpm'	System	22 Sep 2020 18:53:44

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered '14'	(b) (4), (b) (6)	22 Sep 2020 18:53:44

FDA-CBER-2022-1614-0829566

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'breaths/min'	System	22 Sep 2020 18:53:44

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered '105'	(b) (4), (b) (6)	22 Sep 2020 18:53:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:05

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'mmHg'	System	22 Sep 2020 18:53:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:05

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered '78'	(b) (4), (b) (6)	22 Sep 2020 18:53:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'mmHg'	System	22 Sep 2020 18:53:44

Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 07:58:05

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 17:59:59

US3522269

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:05

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 17:59:59

US3522269
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 10 Jun 2021 07:58:05

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:01:26

US3522269

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:58:05

Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
	(b) (4)	
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 18:01:26

US3522269

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:58:05

Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered 'Urine (URINE)'	(b) (4), (b) (6)	22 Sep 2020 18:01:26

US3522269
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 10 Jun 2021 07:58:05
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	22 Sep 2020 18:01:26

US3522269
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 10 Jun 2021 07:58:05

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User closed query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date has been recorded. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 04:59:39
Query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date has been recorded. Kindly update accordingly. ' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 14:13:10
User opened query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date has been recorded. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 11:30:15
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 18:01:26

US3522269

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:58:05

Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 14:13:06
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 18:01:26

US3522269

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:58:05

Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 14:13:06
User entered '13:32'	(b) (4), (b) (6)	22 Sep 2020 18:01:26

US3522269

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:58:05

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	04 Dec 2020 14:13:06
User entered '22 Sep 2020 13:32'	System	22 Sep 2020 18:01:26

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 07:58:05

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:50:24

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:50:24

US3522269

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:05

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)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:50:24

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 18:50:24

FDA-CBER-2022-1614-0829585

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:50:24

US3522269

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered '14:15' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	29 Sep 2020 15:18:52
User entered '13:15'	(b) (4), (b) (6)	22 Sep 2020 18:50:24

US3522269

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:05

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '22 Sep 2020 14:15'	System	29 Sep 2020 15:18:52
User entered '22 Sep 2020 13:15'	System	22 Sep 2020 18:50:24

US3522269

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:05

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:50:24

US3522269

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:05

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'ONCE'	System	22 Sep 2020 18:50:24

US3522269

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 18:50:24

US3522269

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:05

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 18:21:29

US3522269

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:05

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 18:21:29

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered '14:10'	(b) (4), (b) (6)	22 Sep 2020 18:21:29

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '22 Sep 2020 14:10'	System	22 Sep 2020 18:21:29

FDA-CBER-2022-1614-0829595

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 18:21:45

US3522269

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:58:05

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	22 Sep 2020 18:21:45

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 18:21:45

US3522269

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered '14:12'	(b) (4), (b) (6)	22 Sep 2020 18:21:45

US3522269

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:58:05

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '22 Sep 2020 14:12'	System	22 Sep 2020 18:21:45

US3522269

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:05

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	22 Sep 2020 18:21:45

US3522269

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:05

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 18:21:45

US3522269

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 18:21:45

US3522269

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:05

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	22 Sep 2020 18:21:45

US3522269

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:05

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:21:52

US3522269

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:05

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '1'	System	22 Sep 2020 18:21:52

US3522269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 07:58:05
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:50:43', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '7de68ad1-555f-4eed-81d0-04f8b8f52d20'	System	22 Sep 2020 18:51:05
User entered 'Yes (Y)'	System	22 Sep 2020 18:51:05

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:50:50', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '7de68ad1-555f-4eed-81d0-04f8b8f52d20'	System	22 Sep 2020 18:51:05
User entered '98.2'	System	22 Sep 2020 18:51:05

Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:50:55', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '7de68ad1-555f-4eed-81d0-04f8b8f52d20'	System	22 Sep 2020 18:51:05
User entered 'No (N)'	System	22 Sep 2020 18:51:05

Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 07:58:05
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:51:01', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '7de68ad1-555f-4eed-81d0-04f8b8f52d20'	System	22 Sep 2020 18:51:05
User entered '22 Sep 2020 14:51'	System	22 Sep 2020 18:51:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '22 Sep 2020 13:35'	System	22 Sep 2020 18:50:24

Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 07:58:05
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '22 Sep 2020 16:05'	System	22 Sep 2020 18:50:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:57:02', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c7896e7b-b432-425d-b48d-023586a1283f'	System	22 Sep 2020 22:58:02
User entered 'Yes (Y)'	System	22 Sep 2020 22:58:02

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:57:49', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c7896e7b-b432-425d-b48d-023586a1283f'	System	22 Sep 2020 22:58:02
User entered '99.0'	System	22 Sep 2020 22:58:02

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:57:52', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c7896e7b-b432-425d-b48d-023586a1283f'	System	22 Sep 2020 22:58:02
User entered 'No (N)'	System	22 Sep 2020 22:58:02

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:57:59', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c7896e7b-b432-425d-b48d-023586a1283f'	System	22 Sep 2020 22:58:02
User entered '22 Sep 2020 18:57'	System	22 Sep 2020 22:58:02

US3522269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 07:58:05
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '22 Sep 2020 17:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 07:58:05
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 2'	System	22 Sep 2020 18:50:24

US3522269
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 07:58:05
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:26:08', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'e854e9ec-88be-4917-9ff7-41a280e3ed2b'	System	23 Sep 2020 16:27:14
User entered 'Yes (Y)'	System	23 Sep 2020 16:27:14

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:05

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:03', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'e854e9ec-88be-4917-9ff7-41a280e3ed2b'	System	23 Sep 2020 16:27:14
User entered '98.3'	System	23 Sep 2020 16:27:14

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:06', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'e854e9ec-88be-4917-9ff7-41a280e3ed2b'	System	23 Sep 2020 16:27:14
User entered 'No (N)'	System	23 Sep 2020 16:27:14

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:10', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'e854e9ec-88be-4917-9ff7-41a280e3ed2b'	System	23 Sep 2020 16:27:14
User entered '23 Sep 2020 12:27'	System	23 Sep 2020 16:27:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

FDA-CBER-2022-1614-0829626

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 3'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:57:38', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '6666f69f-21e1-402b-bbfc-2cd561f0458f'	System	24 Sep 2020 16:57:58
User entered 'Yes (Y)'	System	24 Sep 2020 16:57:58

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:05

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:57:47', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '6666f69f-21e1-402b-bbfc-2cd561f0458f'	System	24 Sep 2020 16:57:58
User entered '98.8'	System	24 Sep 2020 16:57:58

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:57:50', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '6666f69f-21e1-402b-bbfc-2cd561f0458f'	System	24 Sep 2020 16:57:58
User entered 'No (N)'	System	24 Sep 2020 16:57:58

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:57:53', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '6666f69f-21e1-402b-bbfc-2cd561f0458f'	System	24 Sep 2020 16:57:58
User entered '24 Sep 2020 12:57'	System	24 Sep 2020 16:57:58

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 4'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:36:50', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c0d62dfa-a3c6-40a9-a5a6-2c0f4c034585'	System	25 Sep 2020 16:38:19
User entered 'Yes (Y)'	System	25 Sep 2020 16:38:19

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:05

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:10', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c0d62dfa-a3c6-40a9-a5a6-2c0f4c034585'	System	25 Sep 2020 16:38:19
User entered '98.8'	System	25 Sep 2020 16:38:19

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:12', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c0d62dfa-a3c6-40a9-a5a6-2c0f4c034585'	System	25 Sep 2020 16:38:19
User entered 'No (N)'	System	25 Sep 2020 16:38:19

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:15', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c0d62dfa-a3c6-40a9-a5a6-2c0f4c034585'	System	25 Sep 2020 16:38:19
User entered '25 Sep 2020 12:38'	System	25 Sep 2020 16:38:19

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 5'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:05:32', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '42e6228e-b2bd-4703-87bf-af3120a27191'	System	26 Sep 2020 16:05:47
User entered 'Yes (Y)'	System	26 Sep 2020 16:05:47

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:05

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:05:38', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '42e6228e-b2bd-4703-87bf-af3120a27191'	System	26 Sep 2020 16:05:47
User entered '98.7'	System	26 Sep 2020 16:05:47

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:05:41', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '42e6228e-b2bd-4703-87bf-af3120a27191'	System	26 Sep 2020 16:05:47
User entered 'No (N)'	System	26 Sep 2020 16:05:47

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:05:44', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '42e6228e-b2bd-4703-87bf-af3120a27191'	System	26 Sep 2020 16:05:47
User entered '26 Sep 2020 12:05'	System	26 Sep 2020 16:05:47

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 6'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:36:25', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ebea2675-61fd-4dd7-896e-a7140dab6b60'	System	27 Sep 2020 16:36:48
User entered 'Yes (Y)'	System	27 Sep 2020 16:36:48

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:05

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:36:37', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ebea2675-61fd-4dd7-896e-a7140dab6b60'	System	27 Sep 2020 16:36:48
User entered '98.4'	System	27 Sep 2020 16:36:48

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:36:41', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ebea2675-61fd-4dd7-896e-a7140dab6b60'	System	27 Sep 2020 16:36:48
User entered 'No (N)'	System	27 Sep 2020 16:36:48

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:36:44', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ebea2675-61fd-4dd7-896e-a7140dab6b60'	System	27 Sep 2020 16:36:48
User entered '27 Sep 2020 12:36'	System	27 Sep 2020 16:36:48

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 7'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:03:51', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '8905fa29-b8a2-41ae-bbc4-8ee833dc8a80'	System	28 Sep 2020 16:04:59
User entered 'Yes (Y)'	System	28 Sep 2020 16:04:59

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:05

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:04:31', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '8905fa29-b8a2-41ae-bbc4-8ee833dc8a80'	System	28 Sep 2020 16:04:59
User entered '98.6'	System	28 Sep 2020 16:04:59

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:04:33', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '8905fa29-b8a2-41ae-bbc4-8ee833dc8a80'	System	28 Sep 2020 16:04:59
User entered 'No (N)'	System	28 Sep 2020 16:04:59

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:04:37', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '8905fa29-b8a2-41ae-bbc4-8ee833dc8a80'	System	28 Sep 2020 16:04:59
User entered '28 Sep 2020 12:04'	System	28 Sep 2020 16:04:59

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 07:58:05
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:51:11', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '26b1b6c3-82b5-44dd-b268-d17dd742faf1'	System	22 Sep 2020 18:51:35
User entered 'None (1)'	System	22 Sep 2020 18:51:35

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:51:15', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '26b1b6c3-82b5-44dd-b268-d17dd742faf1'	System	22 Sep 2020 18:51:35
User entered 'No (N)'	System	22 Sep 2020 18:51:35

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:51:19', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '26b1b6c3-82b5-44dd-b268-d17dd742faf1'	System	22 Sep 2020 18:51:35
User entered 'No (N)'	System	22 Sep 2020 18:51:35

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:51:25', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '26b1b6c3-82b5-44dd-b268-d17dd742faf1'	System	22 Sep 2020 18:51:35
User entered 'None (1)'	System	22 Sep 2020 18:51:35

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:51:28', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '26b1b6c3-82b5-44dd-b268-d17dd742faf1'	System	22 Sep 2020 18:51:35
User entered '22 Sep 2020 14:51'	System	22 Sep 2020 18:51:35

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '22 Sep 2020 13:35'	System	22 Sep 2020 18:50:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '22 Sep 2020 16:05'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:58:06', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '29f7d08f-4dbe-470f-9d26-1ba1a2580809'	System	22 Sep 2020 22:58:22
User entered 'None (1)'	System	22 Sep 2020 22:58:22

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:58:09', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '29f7d08f-4dbe-470f-9d26-1ba1a2580809'	System	22 Sep 2020 22:58:22
User entered 'No (N)'	System	22 Sep 2020 22:58:22

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:58:12', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '29f7d08f-4dbe-470f-9d26-1ba1a2580809'	System	22 Sep 2020 22:58:22
User entered 'No (N)'	System	22 Sep 2020 22:58:22

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:58:15', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '29f7d08f-4dbe-470f-9d26-1ba1a2580809'	System	22 Sep 2020 22:58:22
User entered 'None (1)'	System	22 Sep 2020 22:58:22

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:58:18', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '29f7d08f-4dbe-470f-9d26-1ba1a2580809'	System	22 Sep 2020 22:58:22
User entered '22 Sep 2020 18:58'	System	22 Sep 2020 22:58:22

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '22 Sep 2020 17:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 2'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:16', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '16d70a86-dd85-423e-8ee5-4fe36c168997'	System	23 Sep 2020 16:27:31
User entered 'None (1)'	System	23 Sep 2020 16:27:31

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:19', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '16d70a86-dd85-423e-8ee5-4fe36c168997'	System	23 Sep 2020 16:27:31
User entered 'No (N)'	System	23 Sep 2020 16:27:31

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:21', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '16d70a86-dd85-423e-8ee5-4fe36c168997'	System	23 Sep 2020 16:27:31
User entered 'No (N)'	System	23 Sep 2020 16:27:31

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:23', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '16d70a86-dd85-423e-8ee5-4fe36c168997'	System	23 Sep 2020 16:27:31
User entered 'None (1)'	System	23 Sep 2020 16:27:31

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:27', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '16d70a86-dd85-423e-8ee5-4fe36c168997'	System	23 Sep 2020 16:27:31
User entered '23 Sep 2020 12:27'	System	23 Sep 2020 16:27:31

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 07:58:05
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 3'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:57:57', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '5a015f2b-ec61-4b5c-87ec-fe0a0781dc5e'	System	24 Sep 2020 16:58:10
User entered 'None (1)'	System	24 Sep 2020 16:58:10

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:58:00', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '5a015f2b-ec61-4b5c-87ec-fe0a0781dc5e'	System	24 Sep 2020 16:58:10
User entered 'No (N)'	System	24 Sep 2020 16:58:10

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:58:01', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '5a015f2b-ec61-4b5c-87ec-fe0a0781dc5e'	System	24 Sep 2020 16:58:10
User entered 'No (N)'	System	24 Sep 2020 16:58:10

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:58:03', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '5a015f2b-ec61-4b5c-87ec-fe0a0781dc5e'	System	24 Sep 2020 16:58:10
User entered 'None (1)'	System	24 Sep 2020 16:58:10

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:58:06', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '5a015f2b-ec61-4b5c-87ec-fe0a0781dc5e'	System	24 Sep 2020 16:58:10
User entered '24 Sep 2020 12:58'	System	24 Sep 2020 16:58:10

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 4'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:19', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '15a1af6e-b2a8-4bf9-b851-5b0a31d2fcd7'	System	25 Sep 2020 16:38:35
User entered 'None (1)'	System	25 Sep 2020 16:38:35

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:21', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '15a1af6e-b2a8-4bf9-b851-5b0a31d2fcd7'	System	25 Sep 2020 16:38:35
User entered 'No (N)'	System	25 Sep 2020 16:38:35

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:23', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '15a1af6e-b2a8-4bf9-b851-5b0a31d2fcd7'	System	25 Sep 2020 16:38:35
User entered 'No (N)'	System	25 Sep 2020 16:38:35

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:25', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '15a1af6e-b2a8-4bf9-b851-5b0a31d2fcd7'	System	25 Sep 2020 16:38:35
User entered 'None (1)'	System	25 Sep 2020 16:38:35

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:28', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '15a1af6e-b2a8-4bf9-b851-5b0a31d2fcd7'	System	25 Sep 2020 16:38:35
User entered '25 Sep 2020 12:38'	System	25 Sep 2020 16:38:35

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 07:58:05
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 5'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:05:48', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '114815b5-51de-43ef-adf6-3fb3bf476a17'	System	26 Sep 2020 16:05:59
User entered 'None (1)'	System	26 Sep 2020 16:05:59

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:05:50', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '114815b5-51de-43ef-adf6-3fb3bf476a17'	System	26 Sep 2020 16:05:59
User entered 'No (N)'	System	26 Sep 2020 16:05:59

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:05:52', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '114815b5-51de-43ef-adf6-3fb3bf476a17'	System	26 Sep 2020 16:05:59
User entered 'No (N)'	System	26 Sep 2020 16:05:59

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:05:54', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '114815b5-51de-43ef-adf6-3fb3bf476a17'	System	26 Sep 2020 16:05:59
User entered 'None (1)'	System	26 Sep 2020 16:05:59

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:05:56', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '114815b5-51de-43ef-adf6-3fb3bf476a17'	System	26 Sep 2020 16:05:59
User entered '26 Sep 2020 12:05'	System	26 Sep 2020 16:05:59

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 6'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:36:56', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '61a188cd-ca30-48bb-8fc4-098d3d5748b9'	System	27 Sep 2020 16:37:10
User entered 'None (1)'	System	27 Sep 2020 16:37:10

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:36:58', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '61a188cd-ca30-48bb-8fc4-098d3d5748b9'	System	27 Sep 2020 16:37:10
User entered 'No (N)'	System	27 Sep 2020 16:37:10

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:37:00', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '61a188cd-ca30-48bb-8fc4-098d3d5748b9'	System	27 Sep 2020 16:37:10
User entered 'No (N)'	System	27 Sep 2020 16:37:10

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:37:02', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '61a188cd-ca30-48bb-8fc4-098d3d5748b9'	System	27 Sep 2020 16:37:10
User entered 'None (1)'	System	27 Sep 2020 16:37:10

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:37:05', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '61a188cd-ca30-48bb-8fc4-098d3d5748b9'	System	27 Sep 2020 16:37:10
User entered '27 Sep 2020 12:37'	System	27 Sep 2020 16:37:10

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 7'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:04:43', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '118dd802-5985-4cf9-8a78-36d056939dcf'	System	28 Sep 2020 16:05:12
User entered 'None (1)'	System	28 Sep 2020 16:05:12

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:04:45', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '118dd802-5985-4cf9-8a78-36d056939dcf'	System	28 Sep 2020 16:05:12
User entered 'No (N)'	System	28 Sep 2020 16:05:12

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:04:46', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '118dd802-5985-4cf9-8a78-36d056939dcf'	System	28 Sep 2020 16:05:12
User entered 'No (N)'	System	28 Sep 2020 16:05:12

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:04:49', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '118dd802-5985-4cf9-8a78-36d056939dcf'	System	28 Sep 2020 16:05:12
User entered 'None (1)'	System	28 Sep 2020 16:05:12

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:05

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:04:51', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '118dd802-5985-4cf9-8a78-36d056939dcf'	System	28 Sep 2020 16:05:12
User entered '28 Sep 2020 12:04'	System	28 Sep 2020 16:05:12

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:58:05
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 18:50:24

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:58:05
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:51:34', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'b78a039c-e8e0-48c3-9cee-c7e289cfdac1'	System	22 Sep 2020 18:52:01
User entered 'None (0)'	System	22 Sep 2020 18:52:01

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:58:05
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:51:36', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'b78a039c-e8e0-48c3-9cee-c7e289cfdac1'	System	22 Sep 2020 18:52:01
User entered 'None (0)'	System	22 Sep 2020 18:52:01

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:51:39', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'b78a039c-e8e0-48c3-9cee-c7e289cfdac1'	System	22 Sep 2020 18:52:01
User entered 'None (0)'	System	22 Sep 2020 18:52:01

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:58:05
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:51:41', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'b78a039c-e8e0-48c3-9cee-c7e289cfdac1'	System	22 Sep 2020 18:52:01
User entered 'None (0)'	System	22 Sep 2020 18:52:01

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:51:43', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'b78a039c-e8e0-48c3-9cee-c7e289cfdac1'	System	22 Sep 2020 18:52:01
User entered 'None (0)'	System	22 Sep 2020 18:52:01

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:58:05
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:51:45', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'b78a039c-e8e0-48c3-9cee-c7e289cfdac1'	System	22 Sep 2020 18:52:01
User entered 'None (0)'	System	22 Sep 2020 18:52:01

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:51:52', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'b78a039c-e8e0-48c3-9cee-c7e289cfdac1'	System	22 Sep 2020 18:52:01
User entered 'No (N)'	System	22 Sep 2020 18:52:01

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:51:55', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'b78a039c-e8e0-48c3-9cee-c7e289cfdac1'	System	22 Sep 2020 18:52:01
User entered '22 Sep 2020 14:51'	System	22 Sep 2020 18:52:01

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '22 Sep 2020 13:35'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '22 Sep 2020 16:05'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 18:50:24

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:58:05
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:58:25', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2f2b70f7-b15c-4894-b4a8-1883d178ea64'	System	22 Sep 2020 22:58:49
User entered 'No interference with activity (1)'	System	22 Sep 2020 22:58:49

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:58:05
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:58:29', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2f2b70f7-b15c-4894-b4a8-1883d178ea64'	System	22 Sep 2020 22:58:49
User entered 'No interference with activity (1)'	System	22 Sep 2020 22:58:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:58:32', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2f2b70f7-b15c-4894-b4a8-1883d178ea64'	System	22 Sep 2020 22:58:49
User entered 'None (0)'	System	22 Sep 2020 22:58:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:58:34', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2f2b70f7-b15c-4894-b4a8-1883d178ea64'	System	22 Sep 2020 22:58:49
User entered 'None (0)'	System	22 Sep 2020 22:58:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:58:36', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2f2b70f7-b15c-4894-b4a8-1883d178ea64'	System	22 Sep 2020 22:58:49
User entered 'None (0)'	System	22 Sep 2020 22:58:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:58:39', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2f2b70f7-b15c-4894-b4a8-1883d178ea64'	System	22 Sep 2020 22:58:49
User entered 'None (0)'	System	22 Sep 2020 22:58:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:58:42', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2f2b70f7-b15c-4894-b4a8-1883d178ea64'	System	22 Sep 2020 22:58:49
User entered 'No (N)'	System	22 Sep 2020 22:58:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:58:44', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2f2b70f7-b15c-4894-b4a8-1883d178ea64'	System	22 Sep 2020 22:58:49
User entered '22 Sep 2020 18:58'	System	22 Sep 2020 22:58:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '22 Sep 2020 17:00'	System	22 Sep 2020 18:50:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

FDA-CBER-2022-1614-0829748

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:58:05
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 2'	System	22 Sep 2020 18:50:24

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:58:05
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:31', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff94990d-3046-45ee-b149-6eeef0fd1f3a'	System	23 Sep 2020 16:27:50
User entered 'None (0)'	System	23 Sep 2020 16:27:50

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:58:05
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:33', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff94990d-3046-45ee-b149-6eeef0fd1f3a'	System	23 Sep 2020 16:27:50
User entered 'None (0)'	System	23 Sep 2020 16:27:50

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:36', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff94990d-3046-45ee-b149-6eeef0fd1f3a'	System	23 Sep 2020 16:27:50
User entered 'None (0)'	System	23 Sep 2020 16:27:50

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:38', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff94990d-3046-45ee-b149-6eeef0fd1f3a'	System	23 Sep 2020 16:27:50
User entered 'None (0)'	System	23 Sep 2020 16:27:50

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:58:05
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:39', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff94990d-3046-45ee-b149-6eeef0fd1f3a'	System	23 Sep 2020 16:27:50
User entered 'None (0)'	System	23 Sep 2020 16:27:50

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:58:05
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:41', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff94990d-3046-45ee-b149-6eeef0fd1f3a'	System	23 Sep 2020 16:27:50
User entered 'None (0)'	System	23 Sep 2020 16:27:50

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:44', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff94990d-3046-45ee-b149-6eeef0fd1f3a'	System	23 Sep 2020 16:27:50
User entered 'No (N)'	System	23 Sep 2020 16:27:50

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:05

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:46', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff94990d-3046-45ee-b149-6eeef0fd1f3a'	System	23 Sep 2020 16:27:50
User entered '23 Sep 2020 12:27'	System	23 Sep 2020 16:27:50

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 3'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:58:10', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'bd788de3-6cc8-4963-b52a-baa9d567aeab'	System	24 Sep 2020 16:58:33
User entered 'None (0)'	System	24 Sep 2020 16:58:33

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:58:05
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:58:12', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'bd788de3-6cc8-4963-b52a-baa9d567aeab'	System	24 Sep 2020 16:58:33
User entered 'None (0)'	System	24 Sep 2020 16:58:33

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:58:14', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'bd788de3-6cc8-4963-b52a-baa9d567aeab'	System	24 Sep 2020 16:58:33
User entered 'None (0)'	System	24 Sep 2020 16:58:33

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:58:16', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'bd788de3-6cc8-4963-b52a-baa9d567aeab'	System	24 Sep 2020 16:58:33
User entered 'None (0)'	System	24 Sep 2020 16:58:33

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:58:05
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:58:18', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'bd788de3-6cc8-4963-b52a-baa9d567aeab'	System	24 Sep 2020 16:58:33
User entered 'None (0)'	System	24 Sep 2020 16:58:33

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:58:20', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'bd788de3-6cc8-4963-b52a-baa9d567aeab'	System	24 Sep 2020 16:58:33
User entered 'None (0)'	System	24 Sep 2020 16:58:33

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:58:22', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'bd788de3-6cc8-4963-b52a-baa9d567aeab'	System	24 Sep 2020 16:58:33
User entered 'No (N)'	System	24 Sep 2020 16:58:33

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:05

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:58:25', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'bd788de3-6cc8-4963-b52a-baa9d567aeab'	System	24 Sep 2020 16:58:33
User entered '24 Sep 2020 12:58'	System	24 Sep 2020 16:58:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 4'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:32', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c0629f09-04db-4649-9f4d-d5c83961d64b'	System	25 Sep 2020 16:38:49
User entered 'None (0)'	System	25 Sep 2020 16:38:49

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:58:05
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:34', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c0629f09-04db-4649-9f4d-d5c83961d64b'	System	25 Sep 2020 16:38:49
User entered 'None (0)'	System	25 Sep 2020 16:38:49

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:58:05
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:36', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c0629f09-04db-4649-9f4d-d5c83961d64b'	System	25 Sep 2020 16:38:49
User entered 'None (0)'	System	25 Sep 2020 16:38:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:37', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c0629f09-04db-4649-9f4d-d5c83961d64b'	System	25 Sep 2020 16:38:49
User entered 'None (0)'	System	25 Sep 2020 16:38:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:38', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c0629f09-04db-4649-9f4d-d5c83961d64b'	System	25 Sep 2020 16:38:49
User entered 'None (0)'	System	25 Sep 2020 16:38:49

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:58:05
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:40', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c0629f09-04db-4649-9f4d-d5c83961d64b'	System	25 Sep 2020 16:38:49
User entered 'None (0)'	System	25 Sep 2020 16:38:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:42', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c0629f09-04db-4649-9f4d-d5c83961d64b'	System	25 Sep 2020 16:38:49
User entered 'No (N)'	System	25 Sep 2020 16:38:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:05

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:44', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c0629f09-04db-4649-9f4d-d5c83961d64b'	System	25 Sep 2020 16:38:49
User entered '25 Sep 2020 12:38'	System	25 Sep 2020 16:38:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 5'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:06:00', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3b47eb66-766a-493a-991a-51840db48168'	System	26 Sep 2020 16:06:20
User entered 'None (0)'	System	26 Sep 2020 16:06:20

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:58:05
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:06:02', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3b47eb66-766a-493a-991a-51840db48168'	System	26 Sep 2020 16:06:20
User entered 'None (0)'	System	26 Sep 2020 16:06:20

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:06:04', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3b47eb66-766a-493a-991a-51840db48168'	System	26 Sep 2020 16:06:20
User entered 'None (0)'	System	26 Sep 2020 16:06:20

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:06:06', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3b47eb66-766a-493a-991a-51840db48168'	System	26 Sep 2020 16:06:20
User entered 'None (0)'	System	26 Sep 2020 16:06:20

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:58:05
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:06:08', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3b47eb66-766a-493a-991a-51840db48168'	System	26 Sep 2020 16:06:20
User entered 'None (0)'	System	26 Sep 2020 16:06:20

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:58:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:06:09', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3b47eb66-766a-493a-991a-51840db48168'	System	26 Sep 2020 16:06:20
User entered 'None (0)'	System	26 Sep 2020 16:06:20

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:06:12', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3b47eb66-766a-493a-991a-51840db48168'	System	26 Sep 2020 16:06:20
User entered 'No (N)'	System	26 Sep 2020 16:06:20

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:05

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:06:14', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3b47eb66-766a-493a-991a-51840db48168'	System	26 Sep 2020 16:06:20
User entered '26 Sep 2020 12:06'	System	26 Sep 2020 16:06:20

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:58:05
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 6'	System	22 Sep 2020 18:50:24

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:58:05
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:37:10', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ad72ddf9-d8f6-42c4-b141-03d54692512f'	System	27 Sep 2020 16:37:28
User entered 'None (0)'	System	27 Sep 2020 16:37:28

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:58:05
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:37:11', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ad72ddf9-d8f6-42c4-b141-03d54692512f'	System	27 Sep 2020 16:37:28
User entered 'None (0)'	System	27 Sep 2020 16:37:28

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:58:05
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:37:13', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ad72ddf9-d8f6-42c4-b141-03d54692512f'	System	27 Sep 2020 16:37:28
User entered 'None (0)'	System	27 Sep 2020 16:37:28

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:58:05
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:37:15', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ad72ddf9-d8f6-42c4-b141-03d54692512f'	System	27 Sep 2020 16:37:28
User entered 'None (0)'	System	27 Sep 2020 16:37:28

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:58:05
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:37:17', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ad72ddf9-d8f6-42c4-b141-03d54692512f'	System	27 Sep 2020 16:37:28
User entered 'None (0)'	System	27 Sep 2020 16:37:28

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:58:05
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:37:19', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ad72ddf9-d8f6-42c4-b141-03d54692512f'	System	27 Sep 2020 16:37:28
User entered 'None (0)'	System	27 Sep 2020 16:37:28

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:37:22', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ad72ddf9-d8f6-42c4-b141-03d54692512f'	System	27 Sep 2020 16:37:28
User entered 'No (N)'	System	27 Sep 2020 16:37:28

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:05

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:37:24', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ad72ddf9-d8f6-42c4-b141-03d54692512f'	System	27 Sep 2020 16:37:28
User entered '27 Sep 2020 12:37'	System	27 Sep 2020 16:37:28

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:58:05
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 7'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:04:55', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '632908c4-2e08-42b2-92eb-524ed76ab964'	System	28 Sep 2020 16:05:19
User entered 'None (0)'	System	28 Sep 2020 16:05:19

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:58:05
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:04:57', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '632908c4-2e08-42b2-92eb-524ed76ab964'	System	28 Sep 2020 16:05:19
User entered 'None (0)'	System	28 Sep 2020 16:05:19

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:04:58', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '632908c4-2e08-42b2-92eb-524ed76ab964'	System	28 Sep 2020 16:05:19
User entered 'None (0)'	System	28 Sep 2020 16:05:19

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:05:00', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '632908c4-2e08-42b2-92eb-524ed76ab964'	System	28 Sep 2020 16:05:19
User entered 'None (0)'	System	28 Sep 2020 16:05:19

US3522269
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:58:05
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:05:02', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '632908c4-2e08-42b2-92eb-524ed76ab964'	System	28 Sep 2020 16:05:19
User entered 'None (0)'	System	28 Sep 2020 16:05:19

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:05:04', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '632908c4-2e08-42b2-92eb-524ed76ab964'	System	28 Sep 2020 16:05:19
User entered 'None (0)'	System	28 Sep 2020 16:05:19

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:05:07', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '632908c4-2e08-42b2-92eb-524ed76ab964'	System	28 Sep 2020 16:05:19
User entered 'No (N)'	System	28 Sep 2020 16:05:19

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:05

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:05:09', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '632908c4-2e08-42b2-92eb-524ed76ab964'	System	28 Sep 2020 16:05:19
User entered '28 Sep 2020 12:05'	System	28 Sep 2020 16:05:19

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:15
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:58:05

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:12
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 15:16:19

US3522269

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:12
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 15:16:19

Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:58:05

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Sep 2020 15:16:19

FDA-CBER-2022-1614-0829817

US3522269
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:58:05
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 15:16:19

US3522269

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:05

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 15:16:24

US3522269
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:58:05
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '1'	System	29 Sep 2020 15:16:24

US3522269

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:05

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:12
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	06 Oct 2020 14:19:06

US3522269

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:12
User entered '07 Oct 2020' reason for change: Data Entry Error	Kristin Eis (b) (4) (b) (4)	07 Oct 2020 14:49:49
User entered '6 Oct 2020'	Alandra White (b) (4) (b) (4)	06 Oct 2020 14:19:06

US3522269

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:05

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:12
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:08:37
User entered 'Contact Not Made (CONTACT NOT MADE)'	Alandra White (b) (4) (b) (4)	06 Oct 2020 14:19:06

US3522269

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:05

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:12
User entered 'Flu Vaccine received 05 Oct 2020. No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:08:37
User entered 'Call attempted with no answer, left voicemail.'	Alandra White (b) (4) (b) (4)	06 Oct 2020 14:19:06

US3522269

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:05

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:12
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	07 Oct 2020 14:52:34

US3522269

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:05

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '1'	System	07 Oct 2020 14:52:34

US3522269

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:05

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 15:18:14

US3522269

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:12
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 15:18:14

US3522269

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:05

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:18:14

US3522269

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:05

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:36:12
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:18:14

US3522269

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:05

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 15:18:18

US3522269

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:05

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '1'	System	13 Oct 2020 15:18:18

US3522269

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:05

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:03:26

US3522269
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 07:58:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:03:26

US3522269

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:03:26

US3522269
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 07:58:05
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered 'VISIT3'	System	18 Dec 2020 15:03:26

US3522269

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:05

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:04:10

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:04:10

US3522269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:58:05
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:04:10

US3522269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:58:05

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	18 Dec 2020 15:04:10

US3522269

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:05

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:04:10

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:04:10

US3522269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:58:05
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:04:10

US3522269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:58:05

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:04:10

US3522269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:58:05
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	18 Dec 2020 15:04:10

US3522269

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:05

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:04:10

US3522269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:58:05
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	18 Dec 2020 15:04:10

US3522269

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:05

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:04:10

US3522269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:58:05
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	18 Dec 2020 15:04:10

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:04:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	18 Dec 2020 15:04:10

FDA-CBER-2022-1614-0829851

US3522269
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:58:05

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53

US3522269

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53

Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 07:58:05

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:04:16

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:04:16

FDA-CBER-2022-1614-0829855

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:04:20

FDA-CBER-2022-1614-0829856

US3522269

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:05

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:04:20

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:04:20

FDA-CBER-2022-1614-0829858

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	18 Dec 2020 15:04:20

FDA-CBER-2022-1614-0829859

US3522269

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:05

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:36:17
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:04:27

US3522269
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:58:05
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	18 Dec 2020 15:04:27

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 64'	System	21 Aug 2020 13:26:24

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

PRODUCTION RELEASE (v12.003
EAB) (1725)

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
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US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

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Folder: Safety Follow Up Diary (1)

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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 07:58:05

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17
Data entry locked.	System	21 Aug 2020 13:26:24
User entered '21 Oct 2020 00:01'	System	21 Aug 2020 13:26:24

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17
Data entry locked.	System	21 Aug 2020 13:26:24
User entered '25 Oct 2020 23:59'	System	21 Aug 2020 13:26:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 71'	System	21 Aug 2020 13:26:24

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US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3522269

Folder: Safety Follow Up Diary (1)

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Please 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)
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DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 07:58:05

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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Folder: Safety Follow Up Diary (1)

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US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
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Folder: Safety Follow Up Diary (1)

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Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17
Data entry locked.	System	21 Aug 2020 13:26:24
User entered '28 Oct 2020 00:01'	System	21 Aug 2020 13:26:24

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17
Data entry locked.	System	21 Aug 2020 13:26:24
User entered '01 Nov 2020 23:59'	System	21 Aug 2020 13:26:24

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 78'	System	21 Aug 2020 13:26:24

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
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US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Have you been exposed to someone with 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)
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Folder: Safety Follow Up Diary (1)

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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17
Data entry locked.	System	21 Aug 2020 13:26:24
User entered '04 Nov 2020 00:01'	System	21 Aug 2020 13:26:24

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17
Data entry locked.	System	21 Aug 2020 13:26:24
User entered '08 Nov 2020 23:59'	System	21 Aug 2020 13:26:24

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 92'	System	21 Aug 2020 13:26:24

FDA-CBER-2022-1614-0829946

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:58:05
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17

US3522269

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17
Data entry locked.	System	21 Aug 2020 13:26:24
User entered '18 Nov 2020 00:01'	System	21 Aug 2020 13:26:24

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:05

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:23:17
Data entry locked.	System	21 Aug 2020 13:26:24
User entered '22 Nov 2020 23:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 07:58:05

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:59
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 18:40:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:52:27
User entered 'USA-US131-2020-mRNA-1273-P301000005'	System	23 Sep 2020 11:52:16
User entered 'New'	(b) (4), (b) (6)	23 Sep 2020 11:52:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the events of nausea, abdominal pain, and vomiting ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:10:48
User closed query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 10:44:14
Query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' answered with 'Not in for an illness visit. Did not inform until arriving at Visit 2. Swab at visit 2 was negative' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:10:36
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the events of nausea, abdominal pain, and vomiting ' answered with 'Unknown. See queries further down for more detail' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:10:15
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Adverse event

Audit	User	Time (GMT)
User opened query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 06:48:32
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the events of nausea, abdominal pain, and vomiting ' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 14:41:31
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the events.' canceled (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 14:40:46
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the events.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 14:37:25
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 18:58:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 18:58:49
Data point term sent to Coder	System	01 Oct 2020 18:58:04
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 18:57:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 18:57:54
User closed query 'For coding purposes, please split NAUSEA/VOMITING into separate entries' (Site from System).	System	01 Oct 2020 18:57:04
Query 'For coding purposes, please split NAUSEA/VOMITING into separate entries' answered with 'split' (Site from System).	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:57:04
Data point term sent to Coder	System	01 Oct 2020 18:57:00
User entered 'NAUSEA' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Adverse event

Audit	User	Time (GMT)
User opened query 'For coding purposes, please split NAUSEA/VOMITING into separate entries' (Site from System).	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:29:36
Data point term sent to Coder	System	22 Sep 2020 20:18:22
User entered 'Nausea/Vomiting'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint Verified.	(b) (4), (b) (6)	14 Mar 2021 18:00:12
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User closed query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 10:43:46
Query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:09:55
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:09:47
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:09:47
User opened query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 09:25:59
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:28:16
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered '7 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	22 Sep 2020 20:17:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered '15 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	22 Sep 2020 20:17:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered 'Grade 4 (Grade 4)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 07:58:05
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 05:59:36
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'Con procedure was entered as she mentioned procedures being done and did not elaborate. See queries further down for answer.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:11:03
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 09:26:08
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered '1'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered '12 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered '16 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered '0'	Sharon Mathys (b) (4)	22 Sep 2020 20:17:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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Folder: Adverse Events

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Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User closed query 'PV Query: As the last dose of the study drug was given on 21 Aug 2020, and no other doses have been reported, please update the action taken. If study drug has been given since 21 Aug 2020, please update the EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 17:24:40
Query 'PV Query: As the last dose of the study drug was given on 21 Aug 2020, and no other doses have been reported, please update the action taken. If study drug has been given since 21 Aug 2020, please update the EDC accordingly.' answered with '2nd dose given Sep 22, as documented. ' (Site from Safety).	Alayna Wilder (b) (4) (b) (4)	21 Dec 2020 13:32:03
User opened query 'PV Query: As the last dose of the study drug was given on 21 Aug 2020, and no other doses have been reported, please update the action taken. If study drug has been given since 21 Aug 2020, please update the EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 16:46:03
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered 'None (NONE)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 07:58:05
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered '1'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint Verified.	(b) (4), (b) (6)	14 Mar 2021 18:00:20
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 10:07:18
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'In error' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:15:43
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:15:21
User entered '0' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:15:21
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:05:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered '1'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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Form: Adverse Events (1)

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Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 07:58:05
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User closed query 'Per DM CLR: SAE Narrative = SHE ALSO HAD A LOW POTASSIUM AND MAGNESIUM FROM THE VOMITING. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 05:13:12
Query 'Per DM CLR: SAE Narrative = SHE ALSO HAD A LOW POTASSIUM AND MAGNESIUM FROM THE VOMITING. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' answered with 'Not enough information to record those appropriately, participant withdrew from study and refused to allow access to hospital data prior to withdrawing so even if it should be an AE, there is not enough information to properly record.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	27 Jan 2021 19:53:19
User opened query 'Per DM CLR: SAE Narrative = SHE ALSO HAD A LOW POTASSIUM AND MAGNESIUM FROM THE VOMITING. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 02:22:40
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:11:07
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:11:02

PRODUCTION RELEASE (v12.003 EAB) (1725)

FDA-CBER-2022-1614-0830009

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:10:57
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 'Participant has gone no contact with the study on request of a release form for hospital records in Canada. Certified letter has been sent after 5 attempts at contact. Participant no showed Visit 3 as well. It is anticipated that participant will be withdrawn from the study and no further information can be obtained.' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:15:29
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Participant has gone no contact with the study on request of a release form for hospital records in Canada. Certified letter has been sent after 5 attempts at contact. Participant no showed Visit 3 as well. It is anticipated that participant will be withdrawn from the study and no further information can be obtained.' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:15:26
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'No medical history given to site staff prior to onset and site staff was not given access to prior medical records.' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:11:31
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 14:38:25

US3522269
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 07:58:05
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 14:37:59
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 14:37:42
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Narrative

Audit	User	Time (GMT)
User entered 'Nausea onset 7-Sep-2020, gradual and got worse over the following days, vomiting and abdominal pain started 8-Sep-2020, and got worse the next few days. She drove herself to the Windsor Regional Hospital on 11-Sep-2020 or 12-Sep-2020, she could not remember the date. At the time, the vomiting was severe, she vomited any time that she tried to eat something, at least 5-10 times that day, and was dry heaving at several other points The hospital was concerned about gallstones. She had an ultrasound 11-Sep-2020 or 12-Sep-2020 and then she had to wait to get the MRCP until 12-Sep-2020 or 13-Sep-2020, but the results came back showing no gallstones. They did find that she had dilated bile ducts. She also had a low potassium and magnesium from the vomiting. She was given IV replacement. Over the next day or two, her vomiting and nausea resolved, and liquid then solid food was reintroduced and tolerated ok.She was discharged 16-Sep-2020. They did not discharge her on any chronic or ongoing medications. The nausea and vomiting had completely resolved at that point. Zofran 1 tab PO as needed, start date 9/12/20- stop date 9/14/20 (approximate dates) Morphine 1 tab PO as needed, start date 9/12/20- stop date 9/13/20 (approximate dates) Protonix, 1 tab PO daily, start date 9/12/20- stop date 9/16/20 (approximate dates) Potassium, IV, as needed, start date 9/12/20- stop date 9/13/20 (approximate dates) Magnesium IV, as needed, start date 9/12/20- stop date 9/13/20 (approximate dates) Calcium 1 tab PO daily, start date 9/14/20- stop date 9/16/20 (approximate dates)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '1'	System	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '1'	System	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:05

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '0'	System	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:05

AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:12:37
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:52:53
User entered 'USA-US131-2020-mRNA-1273-P301000005'	(b) (4), (b) (6)	23 Sep 2020 11:52:49

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:05

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 20:32:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 20:32:43
Data point term sent to Coder	System	22 Sep 2020 20:31:47
User entered 'Abdominal Pain'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:05

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:05

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:05

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:05

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered '8 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:05

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	22 Sep 2020 20:30:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:05

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered '15 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:32:12
User entered '16 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

PRODUCTION RELEASE (v12.003
EAB) (1725)

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	22 Sep 2020 20:30:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:05

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered 'Grade 4 (Grade 4)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:05

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:05

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:05

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:58:05
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered '1'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:05

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered '12 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:05

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered '16 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:05

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:05

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:05

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:58:05
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:58:05
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:05

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User closed query 'PV Query: As the last dose of the study drug was given on 21 Aug 2020, and no other doses have been reported, please update the action taken. If study drug has been given since 21 Aug 2020, please update the EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 17:25:59
Query 'PV Query: As the last dose of the study drug was given on 21 Aug 2020, and no other doses have been reported, please update the action taken. If study drug has been given since 21 Aug 2020, please update the EDC accordingly.' answered with '2nd dose given Sep 22, as documented. ' (Site from Safety).	Alayna Wilder (b) (4) (b) (4)	21 Dec 2020 13:31:51
User opened query 'PV Query: As the last dose of the study drug was given on 21 Aug 2020, and no other doses have been reported, please update the action taken. If study drug has been given since 21 Aug 2020, please update the EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 16:46:45
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered 'None (NONE)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:05

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:05

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered '1'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:05

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint Verified.	(b) (4), (b) (6)	14 Mar 2021 18:01:07
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered '1' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	14 Dec 2020 20:03:34
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 10:46:43
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'in error' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:16:09
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:16:02
User entered '0' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:16:02
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:05:12
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered '1'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

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Folder: Adverse Events

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Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

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Folder: Adverse Events
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Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User closed query 'Per DM CLR: SAE Narrative = SHE ALSO HAD A LOW POTASSIUM AND MAGNESIUM FROM THE VOMITING. However, please review and verify if these should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 06:23:31
Query 'Per DM CLR: SAE Narrative = SHE ALSO HAD A LOW POTASSIUM AND MAGNESIUM FROM THE VOMITING. However, please review and verify if these should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'Could not confirm or deny her story as she never provided hospital records and ended up not respoinding to communication and being lost to follow up. Decision was made not to log it in as a separate AE as there is not enough data known for start or end dates.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:08:16
User closed query 'Per DM CLR: SAE Narrative = SHE HAD AN ULTRASOUND 11-SEP-2020 OR 12-SEP-2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 06:21:33
Query 'Per DM CLR: SAE Narrative = SHE HAD AN ULTRASOUND 11-SEP-2020 OR 12-SEP-2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'added ultrasound for 11sep2020, though it may be 12 sep2020' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	14 Dec 2020 20:04:27
User opened query 'Per DM CLR: SAE Narrative = SHE ALSO HAD A LOW POTASSIUM AND MAGNESIUM FROM THE VOMITING. However, please review and verify if these should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 05:34:06

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Narrative

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = SHE HAD AN ULTRASOUND 11-SEP-2020 OR 12-SEP-2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 05:33:58
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Sep 2020 20:31:36
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	22 Sep 2020 20:31:36
User entered 'vomiting and abdominal pain started 8-Sep-2020, and got worse the next few days. She drove herself to the Windsor Regional Hospital on 11-Sep-2020 or 12-Sep-2020, she could not remember the date. At the time, the vomiting was severe, she vomited any time that she tried to eat something, at least 5-10 times that day, and was dry heaving at several other points The hospital was concerned about gallstones. She had an ultrasound 11-Sep-2020 or 12-Sep-2020 and then she had to wait to get the MRCP until 12-Sep-2020 or 13-Sep-2020, but the results came back showing no gallstones. They did find that she had dilated bile ducts. She also had a low potassium and magnesium from the vomiting. She was given IV replacement. Over the next day or two, her vomiting and nausea resolved, and liquid then solid food was reintroduced and tolerated ok. She was discharged 16-Sep-2020. They did not discharge her on any chronic or ongoing medications. The nausea and vomiting had completely resolved at that point.' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:31:36
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Sep 2020 20:30:50
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

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Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '1'	System	22 Sep 2020 20:30:50

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '1'	System	22 Sep 2020 20:30:50

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Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:05

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '0'	System	22 Sep 2020 20:30:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:05

AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:13:24
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:49:54
User entered 'USA-US131-2020-mRNA-1273-P301000005'	(b) (4), (b) (6)	02 Oct 2020 12:49:48

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Folder: Adverse Events

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Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User closed query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 06:03:06
Query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' answered with 'Was not informed of this symptom by the participant until at Visit 2. At that time was healthy and an NP swab was taken for the visit and came back negative' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:17:31
User opened query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:38:05
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 18:57:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 18:57:53
Data point term sent to Coder	System	01 Oct 2020 18:56:56

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Adverse event

Audit	User	Time (GMT)
User entered 'VOMITING'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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Folder: Adverse Events

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Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:05

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '8 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered empty.	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	01 Oct 2020 18:56:48

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Folder: Adverse Events

Form: Adverse Events (3)

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Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '15 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered empty.	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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Folder: Adverse Events

Form: Adverse Events (3)

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AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	01 Oct 2020 18:56:48

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Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered 'Grade 4 (Grade 4)'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '0'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '0'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '1'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '12 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

Folder: Adverse Events
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Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '16 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

FDA-CBER-2022-1614-0830073

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Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered empty.	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '0'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '0'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '0'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User closed query 'PV Query: As the last dose of the study drug was given on 21 Aug 2020, and no other doses have been reported, please update the action taken. If study drug has been given since 21 Aug 2020, please update the EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 17:26:13
Query 'PV Query: As the last dose of the study drug was given on 21 Aug 2020, and no other doses have been reported, please update the action taken. If study drug has been given since 21 Aug 2020, please update the EDC accordingly.' answered with '2nd dose given Sep 22, as documented. ' (Site from Safety).	Alayna Wilder (b) (4) (b) (4)	21 Dec 2020 13:32:17
User opened query 'PV Query: As the last dose of the study drug was given on 21 Aug 2020, and no other doses have been reported, please update the action taken. If study drug has been given since 21 Aug 2020, please update the EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 16:47:07
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered 'None (NONE)'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '0'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '1'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '0'	Sharon Mathys (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:05

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered empty.	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:05

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:13:24

Audit	User	Time (GMT)
User entered 'VOMITING AND ABDOMINAL PAIN STARTED 8-SEP-2020, AND GOT WORSE THE NEXT FEW DAYS. SHE DROVE HERSELF TO THE WINDSOR REGIONAL HOSPITAL ON 11-SEP-2020 OR 12-SEP-2020, SHE COULD NOT REMEMBER THE DATE. AT THE TIME, THE VOMITING WAS SEVERE, SHE VOMITED ANY TIME THAT SHE TRIED TO EAT SOMETHING, AT LEAST 5-10 TIMES THAT DAY, AND WAS DRY HEAVING AT SEVERAL OTHER POINTS THE HOSPITAL WAS CONCERNED ABOUT GALLSTONES. SHE HAD AN ULTRASOUND 11-SEP-2020 OR 12-SEP-2020 AND THEN SHE HAD TO WAIT TO GET THE MRCP UNTIL 12-SEP-2020 OR 13-SEP-2020, BUT THE RESULTS CAME BACK SHOWING NO GALLSTONES. THEY DID FIND THAT SHE HAD DILATED BILE DUCTS. SHE ALSO HAD A LOW POTASSIUM AND MAGNESIUM FROM THE VOMITING. SHE WAS GIVEN IV REPLACEMENT. OVER THE NEXT DAY OR TWO, HER VOMITING AND NAUSEA RESOLVED, AND LIQUID THEN SOLID FOOD WAS REINTRODUCED AND TOLERATED OK.SHE WAS DISCHARGED 16-SEP-2020. THEY DID NOT DISCHARGE HER ON ANY CHRONIC OR ONGOING MEDICATIONS. THE NAUSEA AND VOMITING HAD COMPLETELY RESOLVED AT THAT POINT. ZOFRAN 1 TAB PO AS NEEDED, START DATE 9/12/20- STOP DATE 9/14/20 (APPROXIMATE DATES) MORPHINE 1 TAB PO AS NEEDED, START DATE 9/12/20- STOP DATE 9/13/20 (APPROXIMATE DATES) PROTONIX, 1 TAB PO DAILY, START DATE 9/12/20- STOP DATE 9/16/20 (APPROXIMATE DATES) POTASSIUM, IV, AS NEEDED, START DATE 9/12/20- STOP DATE 9/13/20 (APPROXIMATE DATES) MAGNESIUM IV, AS NEEDED, START DATE 9/12/20- STOP DATE 9/13/20 (APPROXIMATE DATES) CALCIUM 1 TAB	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:05

Narrative

Audit	User	Time (GMT)
PO DAILY, START DATE 9/14/20- STOP DATE 9/16/20 (APPROXIMATE DATES)'		

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:05

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '1'	System	01 Oct 2020 18:56:48

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '1'	System	01 Oct 2020 18:56:48

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:05

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '0'	System	01 Oct 2020 18:56:48

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:18
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:20:19

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 20:24:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 20:24:51
Data point term sent to Coder	System	22 Sep 2020 20:23:31
User entered 'Zofran'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:05

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 20:23:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 20:23:10
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:10
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 20:23:01
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:05

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User entered 'Nausea'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:05

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:17:48
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 12:01:43
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:10:37
User entered 'UNKNOWN' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 18:10:29
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 04:11:32
User entered '1'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:05

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 18:10:29
User entered 'tablet (TABLET)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:05

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User entered 'as needed (PRN)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:05

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:05

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User entered '12 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:05

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User entered '14 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:05

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of NAUSEA in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:02:49
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of NAUSEA in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:10:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 18:10:29
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of NAUSEA in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 04:11:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:29:19
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:05

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	22 Sep 2020 20:23:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:05

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	22 Sep 2020 20:23:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:05

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	22 Sep 2020 20:23:01

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 11:01:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 11:01:32
Data point term sent to Coder	System	05 Nov 2020 18:14:53
Coding entries removed.	(b) (4), (b) (6)	05 Nov 2020 18:13:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 05:51:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 05:51:48
Data point term sent to Coder	System	22 Sep 2020 20:26:38
User entered 'Morphine'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:05

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 07:58:05

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:02
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 08:56:19
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). 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), (b) (6)	05 Nov 2020 18:14:00
User entered 'abdominal PAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 18:13:56
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 04:12:02
User entered 'Pain'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:05

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:02
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 12:02:04
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:11:35
User entered 'UNKNOWN' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 18:11:30
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 04:12:10
User entered '1'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

FDA-CBER-2022-1614-0830114

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 18:11:30
User entered 'tablet (TABLET)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:05

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User entered 'as needed (PRN)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:05

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:05

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User entered '12 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:05

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User entered '13 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:05

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	22 Sep 2020 20:25:43

FDA-CBER-2022-1614-0830126

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:05

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:05

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 05:50:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 05:50:16
Data point term sent to Coder	System	07 Oct 2020 14:52:40
User closed query 'CDM-Coding: The trade name PROTONIX can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	System	07 Oct 2020 14:52:26
Query 'CDM-Coding: The trade name PROTONIX can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' answered with 'corrected' (Site from System).	Kristin Eis (b) (4) (b) (4)	07 Oct 2020 14:52:26
User entered 'pantoprazole' reason for change: Data Entry Error	Kristin Eis (b) (4) (b) (4)	07 Oct 2020 14:52:18
User opened query 'CDM-Coding: The trade name PROTONIX can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	Coder Import (b) (4) (b) (4)	23 Sep 2020 10:04:45
Data point term sent to Coder	System	22 Sep 2020 20:27:39

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:05

Name of Medication

Audit	User	Time (GMT)
User entered 'Protonix'	Sharon Mathys (b) (4)	22 Sep 2020 20:27:24
	(b) (4)	

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:05

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:05

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'Nausea'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:05

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:26
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 12:02:15
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:15:27
User entered 'UNKNOWN' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 18:15:02
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 04:12:48
User entered '1'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:05

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 18:15:02
User entered 'tablet (TABLET)'	Sharon Mathys (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:05

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'once daily (QD)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:05

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:05

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered '12 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:05

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered '16 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:05

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:26
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of NAUSEA in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:00:18
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of NAUSEA in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:15:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 18:15:08
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of NAUSEA in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 04:13:27
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:05

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '1'	System	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:05

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '1'	System	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:05

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '804 (804)'	System	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 09:43:50
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 Sep 2020 09:43:50
Data point term sent to Coder	System	22 Sep 2020 20:40:03
User entered 'POTASSIUM IV' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:39:07
Data point term sent to Coder	System	22 Sep 2020 20:35:52
User entered 'Potassium'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:05

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:05

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered 'Electrolyte replacement for vomiting'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:05

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered 'unknown'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:05

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered 'Other (OTHER)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered 'IV bag'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:05

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered 'as needed (PRN)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:05

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:05

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered '12 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:05

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered '13 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:05

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:49
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of VOMITING in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:14:26
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of VOMITING in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' answered with 'mistake' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	30 Oct 2020 15:32:47
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	30 Oct 2020 15:32:34
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of VOMITING in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 04:14:22
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:05

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:05

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:05

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 05:48:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 05:48:57
Data point term sent to Coder	System	22 Sep 2020 20:37:54
User entered 'Magnesium IV'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:05

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:05

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered 'ELECTROLYTE REPLACEMENT For VOMITING' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:43
User entered 'Electrolyte Replacement post Vomiting'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:05

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered 'unknown'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:05

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered 'Other (OTHER)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered 'IV drip'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:05

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered 'as needed (PRN)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:05

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:05

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered '12 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:05

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered '13 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:05

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:52
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of VOMITING in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:14:34
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of VOMITING in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' answered with 'mistake' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	30 Oct 2020 15:33:04
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	30 Oct 2020 15:32:58
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of VOMITING in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 04:14:58
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:05

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:05

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:05

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 21:07:47
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 Sep 2020 21:07:47
Data point term sent to Coder	System	22 Sep 2020 20:39:00
User entered 'Calcium'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:05

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:05

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered 'Electrolyte Replacement for Vomiting'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:05

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 05:46:27
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'Unable to confirm. Participant was lost to follow up and did not provide hospital records. This is what we have.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:07:10
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 06:32:41
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered '1'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:05

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered 'tablet (TABLET)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:05

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered 'once daily (QD)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:05

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:05

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered '14 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:05

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered '16 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:05

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:55
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of VOMITING in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:14:40
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of VOMITING in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' answered with 'mistake' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	30 Oct 2020 15:33:24
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	30 Oct 2020 15:33:13
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of VOMITING in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 04:15:18
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:05

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '1'	System	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:05

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '1'	System	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:05

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered '804 (804)'	System	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:14:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:14:44
Data point term sent to Coder	System	07 Oct 2020 16:10:36
User entered 'Influenza Vaccine'	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

FDA-CBER-2022-1614-0830202

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:05

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User closed query 'Per CDM: Prophylaxis = NO. However, vitamins. Supplements, contraceptives and vaccines are considered for prophylactic use. Please update response to Prophylaxis field as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 03:12:43
Query 'Per CDM: Prophylaxis = NO. However, vitamins. Supplements, contraceptives and vaccines are considered for prophylactic use. Please update response to Prophylaxis field as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	11 Jan 2021 18:41:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	11 Jan 2021 18:41:02
User opened query 'Per CDM: Prophylaxis = NO. However, vitamins. Supplements, contraceptives and vaccines are considered for prophylactic use. Please update response to Prophylaxis field as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 18:08:11
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:05

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered 'Flu vaccination'	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:05

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered '0.5'	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:05

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered 'mL (mL)'	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:05

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered 'once (ONCE)'	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:05

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered 'Intramuscular (INTRAMUSCULAR)'	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:05

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered '5 Oct 2020'	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:05

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered '5 Oct 2020'	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:05

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:05

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:05

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	07 Oct 2020 16:09:51

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 07:58:05

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User entered empty.	System	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 07:58:05

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:20:27

US3522269

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:58:05

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered '11 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	14 Dec 2020 20:03:53

US3522269

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:58:05

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	25 Mar 2021 17:17:27
User closed query 'Per DM CLR: Please specify the location of ULTRASOUND (e.g. ULTRA SOUND ON ABDOMEN, ULTRA SOUND ON THYROID, etc.). Update Concomitant Procedure eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 10:01:21
Query 'Per DM CLR: Please specify the location of ULTRASOUND (e.g. ULTRA SOUND ON ABDOMEN, ULTRA SOUND ON THYROID, etc.). Update Concomitant Procedure eCRF as appropriate. ' answered with 'updated' (Site from DM).	Yaman Ahmed (b) (4) (b) (4)	23 Mar 2021 18:32:20
Signature has been broken.	Yaman Ahmed (b) (4) (b) (4)	23 Mar 2021 18:32:14
User entered 'ABDOMINA ULTRASOUND' reason for change: Data Entry Error	Yaman Ahmed (b) (4) (b) (4)	23 Mar 2021 18:32:14
User opened query 'Per DM CLR: Please specify the location of ULTRASOUND (e.g. ULTRA SOUND ON ABDOMEN, ULTRA SOUND ON THYROID, etc.). Update Concomitant Procedure eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 07:11:38
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered 'ultrasound'	Sharon Mathys (b) (4) (b) (4)	14 Dec 2020 20:03:53

US3522269

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:58:05

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered 'Adverse Event (AE)'	Sharon Mathys (b) (4) (b) (4)	14 Dec 2020 20:03:53

US3522269

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:58:05

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered empty.	Sharon Mathys (b) (4) (b) (4)	14 Dec 2020 20:03:53

US3522269

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User closed query 'Per CDM:As per CCGs, If participant was lost to follow-up, use date of last direct contact (e.g., clinic visit or phone call) with the participant. Last visit of subject to the clinic was on 22 SEP 2020(Visit 2 Day 29) and Phone call was made on 13 OCT 2020. Please review and confirm the date accordingly. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 05:31:33
Query 'Per CDM:As per CCGs, If participant was lost to follow-up, use date of last direct contact (e.g., clinic visit or phone call) with the participant. Last visit of subject to the clinic was on 22 SEP 2020(Visit 2 Day 29) and Phone call was made on 13 OCT 2020. Please review and confirm the date accordingly. ' answered with 'updated accordingly' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 17:38:12
User entered '13 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Dec 2020 17:37:55
User opened query 'Per CDM:As per CCGs, If participant was lost to follow-up, use date of last direct contact (e.g., clinic visit or phone call) with the participant. Last visit of subject to the clinic was on 22 SEP 2020(Visit 2 Day 29) and Phone call was made on 13 OCT 2020. Please review and confirm the date accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 04:17:46
User entered '18 Dec 2020'	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:05:29

US3522269

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:58:05

Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered 'Lost To Follow-up (LOST TO FOLLOW-UP)'	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:05:29

US3522269

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:58:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered empty.	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:05:29

US3522269

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:58:05

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered empty.	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:05:29

US3522269

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:58:05

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered empty.	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:05:29

US3522269

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:58:05

Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered empty.	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:05:29

Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 07:58:05

Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered empty.	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 15:05:29

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'USA-US131-2020-MRNA-1273-P301000005'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:05

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Yes (Y)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:05

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Yes (Y)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:05

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Paul'	System	23 Sep 2020 11:52:16

FDA-CBER-2022-1614-0830240

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:05

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Kilgore'	System	23 Sep 2020 11:52:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6) '	System	23 Sep 2020 11:52:16

FDA-CBER-2022-1614-0830242

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6) '	System	23 Sep 2020 11:52:16

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'MI'	System	23 Sep 2020 11:52:16

FDA-CBER-2022-1614-0830244

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6) '	System	23 Sep 2020 11:52:16

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:27:50
User entered 'US'	System	23 Sep 2020 11:53:18

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered '5'	System	15 Dec 2020 15:35:54
User entered '4'	System	25 Nov 2020 19:11:35
User entered '3'	System	02 Oct 2020 12:50:53
User entered '2'	System	02 Oct 2020 12:28:01
User entered '1'	System	23 Sep 2020 11:53:18

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'USA-US131-2020-MRNA-1273-P301000005'	System	23 Sep 2020 11:52:16

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Yes (Y)'	System	23 Sep 2020 11:52:16

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

FDA-CBER-2022-1614-0830250

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Yes (Y)'	System	23 Sep 2020 11:52:16

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Paul'	System	23 Sep 2020 11:52:16

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Kilgore'	System	23 Sep 2020 11:52:16

FDA-CBER-2022-1614-0830257

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6) '	System	23 Sep 2020 11:52:16

FDA-CBER-2022-1614-0830258

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6) '	System	23 Sep 2020 11:52:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'MI'	System	23 Sep 2020 11:52:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6) '	System	23 Sep 2020 11:52:16

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:27:50
User entered 'US'	System	23 Sep 2020 11:53:18

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:05

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered '5'	System	15 Dec 2020 15:35:54
User entered '4'	System	25 Nov 2020 19:11:35
User entered '3'	System	02 Oct 2020 12:50:53
User entered '2'	System	02 Oct 2020 12:28:01
User entered '1'	System	23 Sep 2020 11:53:18

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:58:05

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
User entered '23/Sep/2020 07:53'	System	23 Sep 2020 11:53:18

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:58:05

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:27:50
User entered '1'	(b) (4), (b) (6)	23 Sep 2020 11:53:18

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'USA-US131-2020-MRNA-1273-P301000005'	System	23 Sep 2020 11:52:16

Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Yes (Y)'	System	23 Sep 2020 11:52:16

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Yes (Y)'	System	23 Sep 2020 11:52:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

FDA-CBER-2022-1614-0830272

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Paul'	System	23 Sep 2020 11:52:16

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Kilgore'	System	23 Sep 2020 11:52:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6) '	System	23 Sep 2020 11:52:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6) '	System	23 Sep 2020 11:52:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'MI'	System	23 Sep 2020 11:52:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6)'	System	23 Sep 2020 11:52:16

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:27:50
User entered 'US'	System	23 Sep 2020 11:53:18

FDA-CBER-2022-1614-0830280

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
	(b) (4)	
User entered '5'	System	15 Dec 2020 15:35:54
User entered '4'	System	25 Nov 2020 19:11:35
User entered '3'	System	02 Oct 2020 12:50:53
User entered '2'	System	02 Oct 2020 12:28:01
User entered '1'	System	23 Sep 2020 11:53:18

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form (2)
Generated On: 10 Jun 2021 07:58:05

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
User entered '02/Oct/2020 12:28'	System	02 Oct 2020 12:28:01

Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form (2)
Generated On: 10 Jun 2021 07:58:05
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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:50:13
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 12:28:01

SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'USA-US131-2020-MRNA-1273-P301000005'	System	23 Sep 2020 11:52:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Yes (Y)'	System	23 Sep 2020 11:52:16

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

FDA-CBER-2022-1614-0830286

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Yes (Y)'	System	23 Sep 2020 11:52:16

Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

FDA-CBER-2022-1614-0830290

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

FDA-CBER-2022-1614-0830291

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Paul'	System	23 Sep 2020 11:52:16

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Kilgore'	System	23 Sep 2020 11:52:16

Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6) '	System	23 Sep 2020 11:52:16

FDA-CBER-2022-1614-0830294

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6) '	System	23 Sep 2020 11:52:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'MI'	System	23 Sep 2020 11:52:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6)'	System	23 Sep 2020 11:52:16

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:27:50
User entered 'US'	System	23 Sep 2020 11:53:18

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:05

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered '5'	System	15 Dec 2020 15:35:54
User entered '4'	System	25 Nov 2020 19:11:35
User entered '3'	System	02 Oct 2020 12:50:53
User entered '2'	System	02 Oct 2020 12:28:01
User entered '1'	System	23 Sep 2020 11:53:18

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form (3)
Generated On: 10 Jun 2021 07:58:05
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
User entered '02/Oct/2020 12:50'	System	02 Oct 2020 12:50:53

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 07:58:05

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 19:11:18
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 12:50:53

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'USA-US131-2020-MRNA-1273-P301000005'	System	23 Sep 2020 11:52:16

Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Yes (Y)'	System	23 Sep 2020 11:52:16

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:05

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Yes (Y)'	System	23 Sep 2020 11:52:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Paul'	System	23 Sep 2020 11:52:16

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Kilgore'	System	23 Sep 2020 11:52:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6) '	System	23 Sep 2020 11:52:16

Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6) '	System	23 Sep 2020 11:52:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'MI'	System	23 Sep 2020 11:52:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6)'	System	23 Sep 2020 11:52:16

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:27:50
User entered 'US'	System	23 Sep 2020 11:53:18

FDA-CBER-2022-1614-0830316

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:05

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered '5'	System	15 Dec 2020 15:35:54
User entered '4'	System	25 Nov 2020 19:11:35
User entered '3'	System	02 Oct 2020 12:50:53
User entered '2'	System	02 Oct 2020 12:28:01
User entered '1'	System	23 Sep 2020 11:53:18

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form (4)
Generated On: 10 Jun 2021 07:58:05
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint Verified.	(b) (4), (b) (6)	14 Mar 2021 17:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered '25/Nov/2020 19:11'	System	25 Nov 2020 19:11:35

Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form (4)
Generated On: 10 Jun 2021 07:58:05

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint Verified.	(b) (4), (b) (6)	14 Mar 2021 17:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:35:39
User entered '1'	(b) (4), (b) (6)	25 Nov 2020 19:11:35

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05

SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'USA-US131-2020-MRNA-1273-P301000005'	System	23 Sep 2020 11:52:16

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Yes (Y)'	System	23 Sep 2020 11:52:16

Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

FDA-CBER-2022-1614-0830323

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:05

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Yes (Y)'	System	23 Sep 2020 11:52:16

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

FDA-CBER-2022-1614-0830326

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:05

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Paul'	System	23 Sep 2020 11:52:16

FDA-CBER-2022-1614-0830328

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Kilgore'	System	23 Sep 2020 11:52:16

PRODUCTION RELEASE (v12.003
EAB) (1725)

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6) '	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:05

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6) '	System	23 Sep 2020 11:52:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'MI'	System	23 Sep 2020 11:52:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6)'	System	23 Sep 2020 11:52:16

US3522269
Folder: SAE USA-US131-2020-MRNA-1273-P301000005
Form: Safety Report Form
Generated On: 10 Jun 2021 07:58:05

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:27:50
User entered 'US'	System	23 Sep 2020 11:53:18

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered '5'	System	15 Dec 2020 15:35:54
User entered '4'	System	25 Nov 2020 19:11:35
User entered '3'	System	02 Oct 2020 12:50:53
User entered '2'	System	02 Oct 2020 12:28:01
User entered '1'	System	23 Sep 2020 11:53:18

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 07:58:05

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint Verified.	(b) (4), (b) (6)	14 Mar 2021 17:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered '15/Dec/2020 07:35'	System	15 Dec 2020 15:35:54

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 07:58:05

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:36:53
DataPoint Verified.	(b) (4), (b) (6)	14 Mar 2021 17:59:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:06:16
User entered '1'	(b) (4), (b) (6)	15 Dec 2020 15:35:54