US3312006 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:00:23

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Form: Participant Creation

Data signed: (b) (4) **05 Apr 2021 17:19:29**

Generated On: 09 Jun 2021 17:00:23

Participant ID	US3312006

mRNA-1273-P301 Completion Guidelines

US3312006

Folder: Screening

Form: Visit Date

Data signed: [(b) (4)] **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: ▓(b) (4)▓ **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

Date of Birth (MMM yyyy)	(b) (6) 1958
Age	62
Age Units	YEARS
Age (Derived)	62
Sex	Female ◯
	Male ⬤
Ethnicity	Hispanic or Latino ◯
	Not Hispanic or Latino ⬤
	Not Reported ◯
	Unknown ◯

Race (Check All That Apply)

White	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

Folder: Screening

Form: Enrollment

Data signed: (b) (4)   **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

Date of Informed Consent *(dd MMM yyyy)*	10 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	

US3312006

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

Did the participant meet all eligibility criteria?　　　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ○

Were any significant conditions reported?   Yes ●

                                                   No ○

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) **15 Apr 2021 19:42:09**

Generated On: 09 Jun 2021 17:00:23

Condition	FRACTURE OF MIDDLE FINGER
Start date (dd MMM yyyy)	UN UNK 1982
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ●
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1982
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1982
Start Year (derived)	1982
Stop Month and Year (derived)	JAN 1982
Stop Year (derived)	1982

Folder: Screening

Form: Medical History (2)

Data signed: ▓▓ (b) (4) ▓▓ **15 Apr 2021 19:42:09**

Generated On: 09 Jun 2021 17:00:23

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

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Folder: Screening

Form: Medical History (3)

Data signed: ░░ (b) (4) ░░ **15 Apr 2021 19:42:09**

Generated On: 09 Jun 2021 17:00:23

Condition	WHITE COAT HYPERTENSION
Start date (dd MMM yyyy)	10 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3312006

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	10 AUG 2020
Time of assessment *(00:00-23:59)*	10:37 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 10:37
Height *(xxx.x)*	71 in
Weight *(xxx.x)*	165 lb
BMI *(xxx.x)*	23.06095 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)] **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

| Was the physical examination performed? | Yes ⬤ |
| | No ◯ |

| Date of examination *(dd MMM yyyy)* | 10 AUG 2020 |

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

Occupational Risk

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

Specify _____

Location and Living Circumstances Risk (check all that apply)

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **15 Feb 2021 21:37:14**

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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	True
Specify	RESIDES IN COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	10 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) ░░░ **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

What was the date of randomization? *(dd MMM yyyy)*	10 AUG 2020
What was the participant's randomization number?	102649

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 ●

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Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4)   **15 Feb 2021 21:37:14**
Generated On: 09 Jun 2021 17:00:23

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)] **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

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)*	10 AUG 2020
Time of assessment *(00:00-23:59)*	10:37 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 10:37
Temperature *(xxx.x)*	98.0 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	55 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4)   **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

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)*	10 AUG 2020
Time of assessment *(00:00-23:59)*	13:27 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 13:27
Temperature *(xxx.x)*	98.5 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	50 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: ⬛ (b) (4) ⬛ **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

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

| Date of examination *(dd MMM yyyy)* | 10 AUG 2020 |

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

Was study treatment given?	Yes ●
	No ○

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

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	10 AUG 2020
What was the treatment time? *(00:00-23:59)*	12:54 (24 HR)
Treatment Date and Time (derived)	10 AUG 2020 12:54
Which arm was used to give treatment?	Left Arm ●
	Right Arm ○
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	10 AUG 2020
Collection time *(00:00-23:59)*	12:07 (24 HR)
Collection date and time (derived)	10 AUG 2020 12:07

US3312006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

Collection date *(dd MMM yyyy)*			10 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:43	10 AUG 2020 11:43
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 21:37:14**
Generated On: 09 Jun 2021 17:00:23

Is the participant continuing to the next visit?   Yes ●

                                                                      No ○

Continuing Flag   1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

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**	98.5 °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	10 AUG 2020 13:35
PC Open Date & Time	10 AUG 2020 13:14
PC Close Date & Time	10 AUG 2020 15:44

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes	●
	No	○
Please record your **TEMPERATURE in °F**		97.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes	○
	No	●

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

PC Time Stamp	10 AUG 2020 19:26
PC Open Date & Time	10 AUG 2020 16:39
PC Close Date & Time	11 AUG 2020 11:59

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 2

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

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

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

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

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

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

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

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

PC Time Stamp	11 AUG 2020 18:27
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:23

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**	98.0 °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	12 AUG 2020 16:20
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:23

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**	98.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	13 AUG 2020 18:41
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 5

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

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

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

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

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

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

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

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

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Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.5 °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	15 AUG 2020 12:14
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ⬤
	No ◯
Please record your **TEMPERATURE in °F**	97.4 °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	16 AUG 2020 13:19
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

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	10 AUG 2020 13:36
PC Open Date & Time	10 AUG 2020 13:14
PC Close Date & Time	10 AUG 2020 15:44

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

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	10 AUG 2020 19:26
PC Open Date & Time	10 AUG 2020 16:39
PC Close Date & Time	11 AUG 2020 11:59

TIMEPOINT	DAY 2

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

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:23

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	12 AUG 2020 16:20
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:23

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	13 AUG 2020 18:42
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:23

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

TIMEPOINT	DAY 6

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

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

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

- ◯ Yes
- ⬤ No

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

- ◯ Yes
- ⬤ No

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

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

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

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	16 AUG 2020 13:20
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

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	10 AUG 2020 13:37
PC Open Date & Time	10 AUG 2020 13:14
PC Close Date & Time	10 AUG 2020 15:44

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:00:23

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	10 AUG 2020 19:27
PC Open Date & Time	10 AUG 2020 16:39
PC Close Date & Time	11 AUG 2020 11:59

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:00:23

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

FDA-CBER-2022-1614-0851961

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:00:23

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 ●

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:00:23

	Yes ◯
PC Time stamp	12 AUG 2020 16:22
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

TIMEPOINT	DAY 4

HEADACHE

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

FATIGUE

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

MUSCLE ACHES ALL OVER BODY

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

JOINT ACHES IN SEVERAL JOINTS

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

NAUSEA/VOMITING

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

CHILLS

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

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

FDA-CBER-2022-1614-0851964

	Yes ◯
PC Time stamp	13 AUG 2020 18:43
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:00:23

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

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:00:23

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

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:23

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 ●

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:00:23

	Yes ◯
PC Time stamp	16 AUG 2020 13:20
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3312006
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 21:37:14**
Generated On: 09 Jun 2021 17:00:23

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 17 AUG 2020 |

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

Comments

If Contact Not Made, please provide Comments _____

US3312006

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

Is the participant continuing to the next visit?　　　　　　　　Yes ⬤

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　1

US3312006
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 21:37:14**
Generated On: 09 Jun 2021 17:00:23

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 24 AUG 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3312006

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: ▓▓▓ (b) (4) ▓▓▓ **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3312006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*	31 AUG 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3312006

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: ▓▓▓ (b) (4) ▓▓▓ **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

Is the participant continuing to the next visit?   Yes ⬤

                                                                                    No ◯

Continuing Flag   1

US3312006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

Was this visit performed?	Yes ⬤
	No ◯

Visit date (dd MMM yyyy)	7 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

Folder OID	VISIT2

US3312006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

Timepoint	Pre-Dose	●
	Post-Dose	○
Were vital signs assessed?	Yes	●
	No	○
Date of assessment *(dd MMM yyyy)*		07 SEP 2020
Time of assessment *(00:00-23:59)*		09:17 (24 HR)
Vital Signs Date and Time (derived)		07 SEP 2020 09:17
Temperature *(xxx.x)*		98.0 F
Route of measurement	Oral	●
	Axillary	○
	Other	○
If Other, specify		
Pulse *(xxx)*		56 beats/min
Pulse units		BPM
Respiratory Rate *(xxx)*		16 breaths/min
Respiratory Rate units		BREATHS/MIN
Systolic Blood Pressure *(xxx)*		146 mmHg
Systolic Blood Pressure units		MMHG
Diastolic Blood Pressure *(xxx)*		90 mmHg
Diastolic Blood Pressure units		MMHG

US3312006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

Timepoint	Pre-Dose ⬭
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ⬭
Date of assessment *(dd MMM yyyy)*	07 SEP 2020
Time of assessment *(00:00-23:59)*	11:07 (24 HR)
Vital Signs Date and Time (derived)	07 SEP 2020 11:07
Temperature *(xxx.x)*	98.1 F
Route of measurement	Oral ⬤
	Axillary ⬭
	Other ⬭
If Other, specify	
Pulse *(xxx)*	51 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	70 mmHg
Diastolic Blood Pressure units	MMHG

US3312006

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: [(b) (4)] **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

Was the physical examination performed?   Yes ⬤

                                                             No ◯

Date of examination *(dd MMM yyyy)*   07 SEP 2020

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

Was study treatment given?   Yes ●
                                                              No ○

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

If reason is Physician Decision, Withdrawal of Consent by
Participant, Protocol Deviation, or Other, specify

What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	7 SEP 2020
What was the treatment time? *(00:00-23:59)*	10:36 (24 HR)
Treatment Date and Time (derived)	7 SEP 2020 10:36
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) **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	07 SEP 2020
Collection time *(00:00-23:59)*	10:01 (24 HR)
Collection date and time (derived)	07 SEP 2020 10:01

US3312006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

Collection date *(dd MMM yyyy)*			07 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:46	07 SEP 2020 09:46
Nasopharyngeal Swab 2	No		

US3312006

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: ▨▨ (b) (4) ▨▨ **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

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	07 SEP 2020 11:08
PC Open Date & Time	07 SEP 2020 10:56
PC Close Date & Time	07 SEP 2020 13:26

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:00:23

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**	98.0 °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	07 SEP 2020 14:43
PC Open Date & Time	07 SEP 2020 14:21
PC Close Date & Time	08 SEP 2020 11:59

TIMEPOINT	DAY 2

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

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

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

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

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

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

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

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

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

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

PC Time Stamp	08 SEP 2020 15:02
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

FDA-CBER-2022-1614-0851988

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:23

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**	98.2 °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	09 SEP 2020 17:11
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

FDA-CBER-2022-1614-0851989

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.4 °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	10 SEP 2020 19:48
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

FDA-CBER-2022-1614-0851990

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:00:23

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**	98.2 °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	11 SEP 2020 12:10
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 6

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	97.1 °F

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

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

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

FDA-CBER-2022-1614-0851992

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:00:23

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	13 SEP 2020 13:27
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

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	07 SEP 2020 11:08
PC Open Date & Time	07 SEP 2020 10:56
PC Close Date & Time	07 SEP 2020 13:26

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

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	07 SEP 2020 14:44
PC Open Date & Time	07 SEP 2020 14:21
PC Close Date & Time	08 SEP 2020 11:59

TIMEPOINT	DAY 2

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

| Is there any **REDNESS AT INJECTION SITE**? | Yes ⚪ |
| | No ⚫ |

| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ⚪ |
| | No ⚫ |

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

PC Time Stamp	08 SEP 2020 15:03
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	09 SEP 2020 17:12
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 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	10 SEP 2020 19:49
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	11 SEP 2020 12:10
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:00:23

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

TIMEPOINT	DAY 7

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

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

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

- Yes ○
- No ●

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

- Yes ○
- No ●

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

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

PC Time Stamp	13 SEP 2020 13:27
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

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	07 SEP 2020 11:09
PC Open Date & Time	07 SEP 2020 10:56
PC Close Date & Time	07 SEP 2020 13:26

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:00:23

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	07 SEP 2020 14:44
PC Open Date & Time	07 SEP 2020 14:21
PC Close Date & Time	08 SEP 2020 11:59

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:00:23

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	08 SEP 2020 15:03
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:23

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	09 SEP 2020 17:12
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

TIMEPOINT	DAY 4

HEADACHE

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

FATIGUE

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

MUSCLE ACHES ALL OVER BODY

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

JOINT ACHES IN SEVERAL JOINTS

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

NAUSEA/VOMITING

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

CHILLS

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

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

FDA-CBER-2022-1614-0852010

	Yes ◯
PC Time stamp	10 SEP 2020 19:49
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 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 ●

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:00:23

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

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:00:23

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	12 SEP 2020 12:31
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

FDA-CBER-2022-1614-0852015

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

US3312006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	14 SEP 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3312006

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: [(b) (4)] **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3312006
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 21:37:14**
Generated On: 09 Jun 2021 17:00:23

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*	21 SEP 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3312006

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

Is the participant continuing to the next visit?   Yes ●

                                                                    No ○

Continuing Flag   1

US3312006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	28 SEP 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3312006

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: ▓▓▓ (b) (4) ▓▓▓ **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

Is the participant continuing to the next visit?   Yes ⬤

                                                                                    No ◯

Continuing Flag   1

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	5 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT3

FDA-CBER-2022-1614-0852024

US3312006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: [(b) (4)] **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

Were vital signs assessed?	Yes ●
	No ◯
Date of assessment *(dd MMM yyyy)*	5 OCT 2020
Time of assessment *(00:00-23:59)*	09:02 (24 HR)
Vital Signs Date and Time (derived)	5 OCT 2020 09:02
Temperature *(xxx.x)*	98.1 F
Route of measurement	Oral ●
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	55 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	97 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312006

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: ████ (b) (4) ████ **15 Feb 2021 21:37:14**

Generated On: 09 Jun 2021 17:00:23

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)*	5 OCT 2020
Collection time *(00:00-23:59)*	09:22 (24 HR)
Collection date and time (derived)	5 OCT 2020 09:22

Data signed: (b) (4) **15 Feb 2021 21:37:14**
Generated On: 09 Jun 2021 17:00:23

Is the participant continuing to the next visit? Yes ●

No ○

Continuing Flag 1

TIMEPOINT	**DAY 64**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 OCT 2020 08:47:04
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 OCT 2020 10:22:17
Patient Cloud Open Date & Time	17 OCT 2020 00:01
Patient Cloud Close Date & Time	21 OCT 2020 23:59

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 OCT 2020 06:52:37
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

FDA-CBER-2022-1614-0852031

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 NOV 2020 06:07:29
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 NOV 2020 06:07:56
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 NOV 2020 13:47:58
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 NOV 2020 06:39:48
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

TIMEPOINT	DAY 117

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

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

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

Date and time of submission	02 DEC 2020 06:35:24
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 DEC 2020 16:37:37
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 DEC 2020 06:28:49
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 DEC 2020 07:09:18
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 DEC 2020 16:32:49
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 JAN 2021 12:00:55
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 JAN 2021 06:38:30
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 JAN 2021 06:37:37
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 JAN 2021 06:08:36
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 FEB 2021 06:38:06
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 FEB 2021 06:23:21
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 FEB 2021 05:42:41
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 FEB 2021 12:20:37
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAR 2021 05:52:32
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 17:03:47

US3312006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) **05 Apr 2021 17:19:30**

Generated On: 09 Jun 2021 17:00:23

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 02 NOV 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3312006

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) **05 Apr 2021 17:19:30**

Generated On: 09 Jun 2021 17:00:23

Is the participant continuing to the next visit?   Yes ⬤

                                                                                                     No ◯

Continuing Flag   1

US3312006

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) **05 Apr 2021 17:19:30**

Generated On: 09 Jun 2021 17:00:23

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

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

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

Comments

If Contact Not Made, please provide Comments _____

US3312006

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) **05 Apr 2021 17:19:30**

Generated On: 09 Jun 2021 17:00:23

Is the participant continuing to the next visit?   Yes ●

                                                                                    No ◯

Continuing Flag   1

US3312006

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) **05 Apr 2021 17:19:30**

Generated On: 09 Jun 2021 17:00:23

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	04 JAN 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3312006

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) **05 Apr 2021 17:19:30**

Generated On: 09 Jun 2021 17:00:23

Is the participant continuing to the next visit?

Yes ●

No ◯

Continuing Flag 1

US3312006

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) **05 Apr 2021 17:19:30**

Generated On: 09 Jun 2021 17:00:23

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	01 FEB 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3312006

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) **05 Apr 2021 17:19:30**

Generated On: 09 Jun 2021 17:00:23

Is the participant continuing to the next visit?   Yes ◯

                                                                    No ⬤

Continuing Flag

US3312006
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 17:00:23

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 ◯ |

US3312006

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

Form: Visit Date

Data signed: (b) (4) **05 Apr 2021 17:19:29**

Generated On: 09 Jun 2021 17:00:23

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	21 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	UNBLND_DECIDE

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

Form: Unblinding

Data signed: ▨ (b) (4) ▨ 05 Apr 2021 17:19:29

Generated On: 09 Jun 2021 17:00:23

Date of updated informed consent *(dd MMM yyyy)*	21 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ⬤
	No ◯
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ◯
	Amendment 6 or later ⬤
Date of unblinding *(dd MMM yyyy)*	21 JAN 2021
Participant randomization assignment	mRNA-1273 ⬤
	Placebo ◯
Actual Dose 1	mRNA-1273 ⬤
	Placebo ◯
	Not Administered ◯
Actual Dose 2	mRNA-1273 ⬤
	Placebo ◯
	Not Administered ◯
Will participant receive mRNA-1273?	Yes ◯
	No ⬤
Placebo Only Flag	══════════
Continuing with mRNA-1273	══════════

US3312006

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

Form: Immunogenicity Assessment

Data signed: (b) (4) **05 Apr 2021 17:19:29**

Generated On: 09 Jun 2021 17:00:23

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	21 JAN 2021
Collection time *(00:00-23:59)*	09:06 (24 HR)
Collection date and time (derived)	21 JAN 2021 09:06

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **05 Apr 2021 17:19:29**

Generated On: 09 Jun 2021 17:00:23

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	21 JAN 2021
Collection time *(00:00 - 23:59)*	09:05
Collection Date and Time (derived)	21 JAN 2021 09:05

US3312006

Folder: Unscheduled (5)

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:00:23

Visit Date	

Please check all assessments that apply for this visit

Physical Exam	
Vital Signs	
Immunogenicity Assessment	
Pregnancy Test	

US3312006

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **12 Mar 2021 15:41:14**

Generated On: 09 Jun 2021 17:00:23

Did the participant experience any adverse events?　　　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

If Yes, enter details on the Adverse Events form.

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: [REDACTED] (b) (4) 15 Apr 2021 19:42:09

Generated On: 09 Jun 2021 17:00:23

AEID	
Adverse event	ELEVATED BLOOD (SYSTOLIC) PRESSURE

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

Was this a Solicited Adverse Reaction? Yes ○ No ●

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

Start date *(dd MMM yyyy)*	10 AUG 2020
Start time *(00:00-23:59)*	13:27 (24 HR)
AE start date and time (derived)	10 AUG 2020 13:27

Ongoing? Yes ○ No ●

If not Ongoing, end date *(dd MMM yyyy)*	07 SEP 2020
End time *(00:00-23:59)*	11:07 (24 HR)
AE End Date and Time (derived)	07 SEP 2020 11:07

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

Is the adverse event serious? Yes ○ No ●

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

Admitted to ICU? Yes ○ No ○ Unknown ○

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

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

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

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

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

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

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

US3312006

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) **15 Apr 2021 19:42:09**

Generated On: 09 Jun 2021 17:00:23

AEID	USA-US300-2021-MRNA-1273-P30 1000022
Adverse event	ACUTE MYOCARDIAL INFARCTION

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)*	09 MAR 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?
Yes ◯
No ⬤

If not Ongoing, end date *(dd MMM yyyy)*	09 MAR 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

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

Is the adverse event serious?
Yes ⬤
No ◯

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

Admitted to ICU?
Yes ◯
No ◯
Unknown ◯

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) **15 Apr 2021 19:42:09**

Generated On: 09 Jun 2021 17:00:23

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

Relationship to investigational product

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Relationship to Study Procedure

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Action taken with investigational product

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

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

Outcome

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

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

Narrative

US3312006

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: [(b) (4)] **15 Apr 2021 19:42:09**

Generated On: 09 Jun 2021 17:00:23

SITE ATTEMPTED TO CONTACT
SUBJECT FOR ROUTINE
FOLLOW-UP, NOTIFIED BY
SPOUSE OF SUBJECT'S DEMISE.
SPOUSE REPORTED THAT ON
09MAR2021 SHE AWOKE TO
FIND SUBJECT HAD DIED
DURING THE NIGHT,
PRONOUNCED BY EMS AT 0726
09MAR2021. AUTOPSY
PERFORMED ON 10MAR2021
REVEALED CAUSE OF DEATH
TO BE HYPERTENSIVE AND
ATHEROSCLEROTIC
CARDIOVASCULAR DISEASE.
HX OF WHITE COAT
HYPERTENSION HTN AND
BRADYCARDIA KNOWN TO
OUR SITE, REPORTEDLY
FOLLOWED BY PCP.

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

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4)   **05 Apr 2021 17:19:29**

Generated On: 09 Jun 2021 17:00:23

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

No ◯

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

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) **05 Apr 2021 17:19:29**

Generated On: 09 Jun 2021 17:00:23

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes ●
	No ○
Indication	HEALTH MAINTENANCE
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 ○

PRODUCTION RELEASE (v12.003 EAB) (1725)

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 1988
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: ⬛ **(b) (4)** ⬛ **05 Apr 2021 17:19:29**

Generated On: 09 Jun 2021 17:00:23

Name of Medication	FISH OIL

Prophylaxis

Yes ⬤

No ◯

Indication	HEALTH MAINTENANCE
Dose per administration	1200

Dose unit

mg ⬤

ug ◯

mL ◯

g ◯

IU ◯

tablet ◯

capsule ◯

puff ◯

Other ◯

If dose unit is Other, specify _____

Frequency

once daily ⬤

twice daily ◯

three times daily ◯

four times daily ◯

every other day ◯

every week ◯

every month ◯

as needed ◯

once ◯

unknown ◯

other ◯

If frequency is Other, specify _____

Route of administration

Oral ⬤

Topical ◯

Subcutaneous ◯

Transdermal ◯

Intraocular ◯

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

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

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 17:19:29

Generated On: 09 Jun 2021 17:00:23

Name of Medication	SEASONAL INFLUENZA VACCINE

Prophylaxis	Yes	●
	No	○

Indication	SEASONAL INFLUENZA VACCINE

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 ◯
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)*	22 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	22 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 ◯

US3312006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **05 Apr 2021 17:19:29**

Generated On: 09 Jun 2021 17:00:23

Were any concomitant procedures performed?   Yes ◯

                                                                                          No ⬤

If yes, please complete Concomitant Procedures form.

Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 09 Jun 2021 17:00:23

Date of dosing discontinuation (dd MMM yyyy) _____

Primary reason for dosing discontinuation

AE (specify) ◯
SAE (specify) ◯
Death ◯
Lost To Follow-up ◯
Physician decision (specify) ◯
Pregnancy ◯
Protocol deviation (specify) ◯
Study Terminated By Sponsor ◯
Withdrawal of consent by ◯
participant (specify)
Due to SARS-COV-2 ◯
Other ◯

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

Date of study discontinuation/completion *(dd MMM yyyy)*	09 MAR 2021
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)*	09 MAR 2021
Was autopsy performed?	Yes ●
	No ◯
	Unknown ◯

US3312006

Folder: SAE USA-US300-2021-MRNA-1273-P301000022

Form: Safety Report Form

Data signed: (b) (4) **15 Apr 2021 19:42:09**

Generated On: 09 Jun 2021 17:00:23

SAEID	USA-US300-2021-MRNA-1273-P30 1000022
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3312006

Folder: SAE USA-US300-2021-MRNA-1273-P301000022

Form: Safety Report Form (1)

Data signed: ████ (b) (4) ████ **15 Apr 2021 19:42:09**

Generated On: 09 Jun 2021 17:00:23

SAEID	USA-US300-2021-MRNA-1273-P30 1000022
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	05/APR/2021 09:20
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312006

Folder: SAE USA-US300-2021-MRNA-1273-P301000022

Form: Safety Report Form (2)

Data signed: ▓▓ (b) (4) ▓▓ **15 Apr 2021 19:42:09**

Generated On: 09 Jun 2021 17:00:23

SAEID	USA-US300-2021-MRNA-1273-P30 1000022
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	14/APR/2021 13:11
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

Audit

US3312006 (Prod: Johnson County Clin-Trials)

US3312006
Form: Participant Creation
Generated On: 09 Jun 2021 17:00:23

Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:56:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'US3312006'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 17:04:22

US3312006
Form: Participant Creation
Generated On: 09 Jun 2021 17:00:23

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55

US3312006
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:00:23
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:00:32

US3312006
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:00:23

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 17:04:23

US3312006
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:00:32

US3312006
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:00:23
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered 'SCRN'	System	10 Aug 2020 18:00:32

US3312006
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:00:23
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered (b) (6) 1958'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 17:04:23

US3312006
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:00:23

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '62'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:43:19

US3312006
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:00:23
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered 'YEARS'	System	12 Aug 2020 13:43:19

US3312006
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:00:23

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered '62'	System	10 Aug 2020 18:00:58

US3312006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:23

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Male (M)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:43:19

US3312006
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:00:23
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:43:19

US3312006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:23

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '1'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:43:19

US3312006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:23

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '0'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:43:19

US3312006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:23

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '0'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:43:19

US3312006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:23

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '0'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:43:19

US3312006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:23

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '0'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:43:19

US3312006
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:00:23
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '0'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:43:19

US3312006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:23

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered empty.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:43:19

US3312006
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:00:23
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '0'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:43:19

US3312006
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:00:23
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '0'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:43:19

US3312006

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:23

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '10 Aug 2020'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:00:58

US3312006

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:23

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered 'Aug 2020'	System	10 Aug 2020 18:00:58

US3312006
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:00:23
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered '2020'	System	10 Aug 2020 18:00:58

US3312006
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:00:23
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Amendment 1 (1)'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:00:58

US3312006
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:00:23

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:00:58

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered empty.	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:00:58

Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:00:23
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered empty.	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:00:58

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:00:58

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US3312006

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:23

If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 17:04:23

US3312006
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:00:23
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered '1'	System	10 Aug 2020 18:01:05

US3312006

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:00:23

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:01:05

US3312006

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:00:23

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:43:40

US3312006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hand fracture, LLT: Fractured finger - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 09:06:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 09:06:23
Data point term sent to Coder	System	12 Aug 2020 13:45:19
User entered 'fracture of middle finger'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:44:28

US3312006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'un UNK 1982'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:44:28

US3312006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:23

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '0'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:44:28

US3312006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:23

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:44:28

US3312006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'un UNK 1982'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:44:28

US3312006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:23

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '0'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:44:28

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered 'Jan 1982'	System	12 Aug 2020 13:44:28

US3312006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:23

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered '1982'	System	12 Aug 2020 13:44:28

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered 'Jan 1982'	System	12 Aug 2020 13:44:28

US3312006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:23

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered '1982'	System	12 Aug 2020 13:44:28

US3312006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:00:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac disorders, signs and symptoms NEC, HLT: Cardiac signs and symptoms NEC, PT: Athletic heart syndrome, LLT: Athletic bradycardia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:51:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:51:13
Data point term sent to Coder	System	12 Aug 2020 13:45:21
User entered 'athletis bradycardia'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:45:02

US3312006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:00:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'un UNK 1980'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:45:02

US3312006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:00:23

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '0'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:45:02

US3312006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:00:23

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:45:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered empty.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:45:02

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US3312006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:00:23

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '0'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:45:02

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:00:23

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered 'Jan 1980'	System	12 Aug 2020 13:45:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered '1980'	System	12 Aug 2020 13:45:02

US3312006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:00:23

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered empty.	System	12 Aug 2020 13:45:02

US3312006
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:00:23

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered empty.	System	12 Aug 2020 13:45:02

US3312006
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:00:23
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Apr 2021 19:42:09
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: White coat hypertension, LLT: White coat hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 20:26:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 20:26:09
Data point term sent to Coder	System	13 Apr 2021 20:25:36
User entered 'WHITE COAT HYPERTENSION'	Karol Moore (b) (4) (b) (4)	13 Apr 2021 20:24:57

US3312006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:00:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Apr 2021 19:42:09
User entered '10 Aug 2020'	Karol Moore (b) (4) (b) (4)	13 Apr 2021 20:24:57

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Apr 2021 19:42:09
User entered '0'	Karol Moore (b) (4) (b) (4)	13 Apr 2021 20:24:57

US3312006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:00:23

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Apr 2021 19:42:09
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	13 Apr 2021 20:24:57

US3312006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Apr 2021 19:42:09
User entered empty.	Karol Moore (b) (4) (b) (4)	13 Apr 2021 20:24:57

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:00:23

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:42:09
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	13 Apr 2021 20:24:57
	(b) (4)	

US3312006
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:00:23
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered 'Aug 2020'	System	13 Apr 2021 20:24:57

US3312006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:00:23

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered '2020'	System	13 Apr 2021 20:24:57

US3312006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:00:23

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered empty.	System	13 Apr 2021 20:24:57

US3312006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:00:23

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered empty.	System	13 Apr 2021 20:24:57

US3312006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:23

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:45:59

US3312006
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:00:23
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '10 Aug 2020'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:45:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '10:37'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:45:59

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered '10 Aug 2020 10:37'	System	12 Aug 2020 13:45:59

FDA-CBER-2022-1614-0852152

US3312006
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:00:23

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '71' in	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:45:59
DataPoint set to visible.	System	10 Aug 2020 18:01:05

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '165' lb	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:45:59
DataPoint set to visible.	System	10 Aug 2020 18:01:05

US3312006
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:00:23
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: User entered '23.06095'	System	16 Sep 2020 23:50:07
User entered '23.1'	System	12 Aug 2020 13:45:59
DataPoint set to visible.	System	10 Aug 2020 18:01:05

US3312006
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:00:23
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered 'kg/m2'	System	12 Aug 2020 13:45:59
DataPoint set to visible.	System	10 Aug 2020 18:01:05

US3312006
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:00:23

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:45:59

US3312006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:23

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Oral (Oral)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:45:59

US3312006
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:00:23
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered empty.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:45:59

US3312006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:23

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:45:59

US3312006
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:00:23
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered 'bpm'	System	12 Aug 2020 13:45:59

US3312006
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:00:23
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:45:59

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered 'breaths/min'	System	12 Aug 2020 13:45:59

US3312006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:23

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:45:59

US3312006
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:00:23
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered 'mmHg'	System	12 Aug 2020 13:45:59

US3312006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:23

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:45:59

US3312006
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:00:23
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered 'mmHg'	System	12 Aug 2020 13:45:59

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55

US3312006
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:00:23

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55

Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 17:00:23

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:47:10

US3312006

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:23

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:15
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	08 Sep 2020 09:54:08
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	07 Sep 2020 15:39:12
User entered '10 Aug 2020'	Kelly Moen (b) (4)	12 Aug 2020 13:47:10

US3312006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:51:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:51:35

US3312006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:23

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:51:35

US3312006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:23

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:51:35

US3312006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:51:35

US3312006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:23

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:51:35

US3312006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:23

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:51:35

US3312006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:23

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:51:35

US3312006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:23

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:51:35

US3312006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:23

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:51:35

US3312006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:23

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:51:35

US3312006
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:00:23
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:51:35

US3312006
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:00:23
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered empty.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:51:35

US3312006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:23

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '0'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:51:35

US3312006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:23

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '0'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:51:35

US3312006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:23

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '0'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:51:35

US3312006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:23

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '0'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:51:35

US3312006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:23

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '0'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:51:35

US3312006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '0'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:51:35

US3312006
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:00:23
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '1'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:51:35

US3312006
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:00:23
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'resides in community with ongoing person to person transmission'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:51:35

US3312006
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:00:23

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:01:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '10 Aug 2020'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:01:26

US3312006

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:01:26

US3312006
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:00:23
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User entered 'VISIT1'	System	10 Aug 2020 18:01:26

US3312006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 17:19:24

US3312006
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:00:23

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:19:16
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:19:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 17:19:24
User entered '102649' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 17:19:24

US3312006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:23

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:15
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 17:19:24

US3312006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:23

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:02:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:02:36
User entered 'No (N)' reason for change: Data Entry Error	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:02:36
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:02:15
User entered empty.	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:02:15

US3312006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:23

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:02:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:02:36
User entered 'No (N)' reason for change: Data Entry Error	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:02:36
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:02:15
User entered empty.	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:02:15

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US3312006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:02:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:02:36
User entered 'No (N)' reason for change: Data Entry Error	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:02:36
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:02:15
User entered empty.	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:02:15

US3312006
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:00:23
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:02:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:02:36
User entered 'No (N)' reason for change: Data Entry Error	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:02:36
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:02:15
User entered empty.	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:02:15

US3312006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:23

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:02:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:02:36
User entered 'No (N)' reason for change: Data Entry Error	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:02:36
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:02:15
User entered empty.	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:02:15

US3312006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:23

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

US3312006
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:00:23
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

US3312006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:23

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

US3312006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:23

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

US3312006
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:00:23
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User accepted default value 'Pre-Dose (PREDOSE)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

US3312006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:23

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

US3312006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:23

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '10 Aug 2020'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

US3312006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '10:37'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

US3312006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:23

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User entered '10 Aug 2020 10:37'	System	12 Aug 2020 13:54:01

US3312006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:23

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '98.0' F	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

US3312006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:23

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Oral (Oral)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

US3312006
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:00:23
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered empty.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

US3312006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:23

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '55'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:23

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User entered 'bpm'	System	12 Aug 2020 13:54:01

US3312006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:23

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '14'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User entered 'breaths/min'	System	12 Aug 2020 13:54:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:23

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '137' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	27 Jan 2021 23:09:48
User entered '151'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User entered 'mmHg'	System	12 Aug 2020 13:54:01

US3312006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:23

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '78' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	27 Jan 2021 23:09:48
User entered '83'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

US3312006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User entered 'mmHg'	System	12 Aug 2020 13:54:01

US3312006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:23

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

US3312006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:23

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:23

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User accepted default value 'Post-Dose (POSTDOSE)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

US3312006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:23

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 13:54:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 13:54:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:06
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 13:54:01
User entered empty.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

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US3312006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:23

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '10 Aug 2020'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:15
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	17 Aug 2020 07:03:40
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	12 Aug 2020 13:54:01
User entered '13:27'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:23

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User entered '10 Aug 2020 13:27'	System	12 Aug 2020 13:54:01

US3312006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:23

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '98.5' F	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

US3312006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:23

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Oral (Oral)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

US3312006
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:00:23
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered empty.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:23

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '50' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	27 Jan 2021 23:09:48
User entered '49'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

US3312006
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:00:23
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User entered 'bpm'	System	12 Aug 2020 13:54:01

US3312006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:23

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '14'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User entered 'breaths/min'	System	12 Aug 2020 13:54:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:23

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '149' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	27 Jan 2021 23:09:48
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 15:31:50
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:47
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	12 Aug 2020 13:54:01
User entered '160'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:23

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User entered 'mmHg'	System	12 Aug 2020 13:54:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:23

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '74' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	27 Jan 2021 23:09:48
User entered '89'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 13:54:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User entered 'mmHg'	System	12 Aug 2020 13:54:01

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:23

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:03:09

FDA-CBER-2022-1614-0852243

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:23

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '10 Aug 2020'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:03:09

US3312006
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:00:23
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:03:17

US3312006
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:00:23

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered empty.	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:03:17

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:23

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered empty.	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:03:17

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 18:03:17

FDA-CBER-2022-1614-0852248

US3312006
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '10 Aug 2020'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:03:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '12:54'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:03:17

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User entered '10 Aug 2020 12:54'	System	10 Aug 2020 18:03:17

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:03:17

US3312006
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:00:23
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User entered 'ONCE'	System	10 Aug 2020 18:03:17

US3312006
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:00:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 18:03:17

US3312006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:23

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:06:44

US3312006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:23

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '10 Aug 2020'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:06:44

US3312006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '12:07'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:06:44

US3312006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:23

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User entered '10 Aug 2020 12:07'	System	12 Aug 2020 14:06:44

US3312006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:00:23

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '10 Aug 2020'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:07:17

US3312006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:23

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:07:17

US3312006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:23

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:07:17

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '11:43'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:07:17

FDA-CBER-2022-1614-0852262

US3312006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:23

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User entered '10 Aug 2020 11:43'	System	12 Aug 2020 14:07:17

US3312006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:23

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:07:17

US3312006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:23

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:07:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered empty.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:07:17

US3312006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:23

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User entered empty.	System	12 Aug 2020 14:07:17

US3312006
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 17:00:23

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:10:03

US3312006
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 17:00:23
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User entered '1'	System	12 Aug 2020 14:10:03

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T13:34:19', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '6b4c99fd-e0d1-41fc-91f7-1fd803120549'	System	10 Aug 2020 18:35:20
User entered 'Yes (Y)'	System	10 Aug 2020 18:35:20

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T13:34:35', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '6b4c99fd-e0d1-41fc-91f7-1fd803120549'	System	10 Aug 2020 18:35:20
User entered '98.5'	System	10 Aug 2020 18:35:20

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T13:34:46', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '6b4c99fd-e0d1-41fc-91f7-1fd803120549'	System	10 Aug 2020 18:35:20
User entered 'No (N)'	System	10 Aug 2020 18:35:20

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:00:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T13:35:17', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '6b4c99fd-e0d1-41fc-91f7-1fd803120549'	System	10 Aug 2020 18:35:20
User entered '10 Aug 2020 13:35'	System	10 Aug 2020 18:35:20

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:00:23
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '10 Aug 2020 13:14'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:00:23
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '10 Aug 2020 15:44'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:00:23
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T19:25:45', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'b17f4e56-3ae9-4787-bd15-0dea52e0ca6b'	System	11 Aug 2020 00:26:06
User entered 'Yes (Y)'	System	11 Aug 2020 00:26:06

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T19:25:52', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'b17f4e56-3ae9-4787-bd15-0dea52e0ca6b'	System	11 Aug 2020 00:26:06
User entered '97.0'	System	11 Aug 2020 00:26:06

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T19:25:57', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'b17f4e56-3ae9-4787-bd15-0dea52e0ca6b'	System	11 Aug 2020 00:26:06
User entered 'No (N)'	System	11 Aug 2020 00:26:06

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:00:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T19:26:01', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'b17f4e56-3ae9-4787-bd15-0dea52e0ca6b'	System	11 Aug 2020 00:26:06
User entered '10 Aug 2020 19:26'	System	11 Aug 2020 00:26:06

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '10 Aug 2020 16:39'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 2'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:00:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-11T18:26:45', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '3c069e88-d4f2-483b-b9bb-beb40ac282f1'	System	11 Aug 2020 23:27:05
User entered 'Yes (Y)'	System	11 Aug 2020 23:27:05

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:00:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-11T18:26:51', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '3c069e88-d4f2-483b-b9bb-beb40ac282f1'	System	11 Aug 2020 23:27:05
User entered '97.8'	System	11 Aug 2020 23:27:05

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-11T18:26:56', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '3c069e88-d4f2-483b-b9bb-beb40ac282f1'	System	11 Aug 2020 23:27:05
User entered 'No (N)'	System	11 Aug 2020 23:27:05

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:00:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-11T18:27:02', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '3c069e88-d4f2-483b-b9bb-beb40ac282f1'	System	11 Aug 2020 23:27:05
User entered '11 Aug 2020 18:27'	System	11 Aug 2020 23:27:05

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:00:23
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 3'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-12T16:19:47', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '178bd2f8-4d78-497c-81b8-6feeb8db91a0'	System	12 Aug 2020 21:20:04
User entered 'Yes (Y)'	System	12 Aug 2020 21:20:04

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-12T16:19:53', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '178bd2f8-4d78-497c-81b8-6feeb8db91a0'	System	12 Aug 2020 21:20:04
User entered '98.0'	System	12 Aug 2020 21:20:04

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-12T16:19:57', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '178bd2f8-4d78-497c-81b8-6feeb8db91a0'	System	12 Aug 2020 21:20:04
User entered 'No (N)'	System	12 Aug 2020 21:20:04

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:00:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-12T16:20:01', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '178bd2f8-4d78-497c-81b8-6feeb8db91a0'	System	12 Aug 2020 21:20:04
User entered '12 Aug 2020 16:20'	System	12 Aug 2020 21:20:04

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 4'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-13T18:41:25', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '362865db-8790-456a-bbda-3a2534ba7dc7'	System	13 Aug 2020 23:41:44
User entered 'Yes (Y)'	System	13 Aug 2020 23:41:44

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:00:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-13T18:41:31', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '362865db-8790-456a-bbda-3a2534ba7dc7'	System	13 Aug 2020 23:41:44
User entered '98.5'	System	13 Aug 2020 23:41:44

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-13T18:41:35', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '362865db-8790-456a-bbda-3a2534ba7dc7'	System	13 Aug 2020 23:41:44
User entered 'No (N)'	System	13 Aug 2020 23:41:44

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:00:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-13T18:41:40', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '362865db-8790-456a-bbda-3a2534ba7dc7'	System	13 Aug 2020 23:41:44
User entered '13 Aug 2020 18:41'	System	13 Aug 2020 23:41:44

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 5'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:00:23
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-14T12:16:56', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '32c44d71-b038-4f1f-bef5-f5aad577461d'	System	14 Aug 2020 17:18:09
User entered 'Yes (Y)'	System	14 Aug 2020 17:18:09

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:00:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-14T12:17:01', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '32c44d71-b038-4f1f-bef5-f5aad577461d'	System	14 Aug 2020 17:18:09
User entered '97.7'	System	14 Aug 2020 17:18:09

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-14T12:17:05', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '32c44d71-b038-4f1f-bef5-f5aad577461d'	System	14 Aug 2020 17:18:09
User entered 'No (N)'	System	14 Aug 2020 17:18:09

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:00:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-14T12:17:09', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '32c44d71-b038-4f1f-bef5-f5aad577461d'	System	14 Aug 2020 17:18:09
User entered '14 Aug 2020 12:17'	System	14 Aug 2020 17:18:09

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:00:23
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 6'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:00:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-15T12:14:27', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '232fc5c0-6287-4ec5-8455-c021a0786119'	System	15 Aug 2020 17:14:41
User entered 'Yes (Y)'	System	15 Aug 2020 17:14:41

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:00:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-15T12:14:32', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '232fc5c0-6287-4ec5-8455-c021a0786119'	System	15 Aug 2020 17:14:41
User entered '97.5'	System	15 Aug 2020 17:14:41

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-15T12:14:36', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '232fc5c0-6287-4ec5-8455-c021a0786119'	System	15 Aug 2020 17:14:41
User entered 'No (N)'	System	15 Aug 2020 17:14:41

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:00:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-15T12:14:39', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '232fc5c0-6287-4ec5-8455-c021a0786119'	System	15 Aug 2020 17:14:41
User entered '15 Aug 2020 12:14'	System	15 Aug 2020 17:14:41

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:00:23
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 7'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:00:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-16T13:19:30', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e1426545-58c4-491e-9f47-2f4d4cfe2f94'	System	16 Aug 2020 18:19:47
User entered 'Yes (Y)'	System	16 Aug 2020 18:19:47

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:00:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-16T13:19:38', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e1426545-58c4-491e-9f47-2f4d4cfe2f94'	System	16 Aug 2020 18:19:47
User entered '97.4'	System	16 Aug 2020 18:19:47

US3312006
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:00:23
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-16T13:19:42', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e1426545-58c4-491e-9f47-2f4d4cfe2f94'	System	16 Aug 2020 18:19:47
User entered 'No (N)'	System	16 Aug 2020 18:19:47

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:00:23

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-16T13:19:45', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e1426545-58c4-491e-9f47-2f4d4cfe2f94'	System	16 Aug 2020 18:19:47
User entered '16 Aug 2020 13:19'	System	16 Aug 2020 18:19:47

US3312006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 18:03:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T13:35:30', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '3af45c45-e895-42a8-bc76-ef01e4b5d90e'	System	10 Aug 2020 18:36:20
User entered 'None (1)'	System	10 Aug 2020 18:36:20

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T13:35:34', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '3af45c45-e895-42a8-bc76-ef01e4b5d90e'	System	10 Aug 2020 18:36:20
User entered 'No (N)'	System	10 Aug 2020 18:36:20

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T13:36:04', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '3af45c45-e895-42a8-bc76-ef01e4b5d90e'	System	10 Aug 2020 18:36:20
User entered 'No (N)'	System	10 Aug 2020 18:36:20

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T13:36:12', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '3af45c45-e895-42a8-bc76-ef01e4b5d90e'	System	10 Aug 2020 18:36:20
User entered 'None (1)'	System	10 Aug 2020 18:36:20

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:00:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T13:36:18', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '3af45c45-e895-42a8-bc76-ef01e4b5d90e'	System	10 Aug 2020 18:36:20
User entered '10 Aug 2020 13:36'	System	10 Aug 2020 18:36:20

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:00:23
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '10 Aug 2020 13:14'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:00:23
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '10 Aug 2020 15:44'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T19:26:09', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '95eabd43-82a4-4d42-ab7a-ee200cb31670'	System	11 Aug 2020 00:26:40
User entered 'None (1)'	System	11 Aug 2020 00:26:40

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T19:26:26', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '95eabd43-82a4-4d42-ab7a-ee200cb31670'	System	11 Aug 2020 00:26:40
User entered 'No (N)'	System	11 Aug 2020 00:26:40

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T19:26:30', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '95eabd43-82a4-4d42-ab7a-ee200cb31670'	System	11 Aug 2020 00:26:40
User entered 'No (N)'	System	11 Aug 2020 00:26:40

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T19:26:34', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '95eabd43-82a4-4d42-ab7a-ee200cb31670'	System	11 Aug 2020 00:26:40
User entered 'None (1)'	System	11 Aug 2020 00:26:40

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:00:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T19:26:39', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '95eabd43-82a4-4d42-ab7a-ee200cb31670'	System	11 Aug 2020 00:26:40
User entered '10 Aug 2020 19:26'	System	11 Aug 2020 00:26:40

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '10 Aug 2020 16:39'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:00:23
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 2'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-11T18:27:59', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9348fef1-9890-49b3-923c-20685ae1d1e2'	System	11 Aug 2020 23:28:54
User entered 'Does not interfere with activity (2)'	System	11 Aug 2020 23:28:54

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-11T18:28:05', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9348fef1-9890-49b3-923c-20685ae1d1e2'	System	11 Aug 2020 23:28:54
User entered 'No (N)'	System	11 Aug 2020 23:28:54

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-11T18:28:08', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9348fef1-9890-49b3-923c-20685ae1d1e2'	System	11 Aug 2020 23:28:54
User entered 'No (N)'	System	11 Aug 2020 23:28:54

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-11T18:28:13', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9348fef1-9890-49b3-923c-20685ae1d1e2'	System	11 Aug 2020 23:28:54
User entered 'None (1)'	System	11 Aug 2020 23:28:54

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:00:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-11T18:28:46', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9348fef1-9890-49b3-923c-20685ae1d1e2'	System	11 Aug 2020 23:28:54
User entered '11 Aug 2020 18:28'	System	11 Aug 2020 23:28:54

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:00:23
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 3'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-12T16:20:15', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '5ba1674b-9e84-4212-9cc8-60bae31b06dc'	System	12 Aug 2020 21:20:50
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 21:20:50

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-12T16:20:19', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '5ba1674b-9e84-4212-9cc8-60bae31b06dc'	System	12 Aug 2020 21:20:50
User entered 'No (N)'	System	12 Aug 2020 21:20:50

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-12T16:20:37', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '5ba1674b-9e84-4212-9cc8-60bae31b06dc'	System	12 Aug 2020 21:20:50
User entered 'No (N)'	System	12 Aug 2020 21:20:50

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-12T16:20:41', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '5ba1674b-9e84-4212-9cc8-60bae31b06dc'	System	12 Aug 2020 21:20:50
User entered 'None (1)'	System	12 Aug 2020 21:20:50

FDA-CBER-2022-1614-0852354

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:00:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-12T16:20:47', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '5ba1674b-9e84-4212-9cc8-60bae31b06dc'	System	12 Aug 2020 21:20:50
User entered '12 Aug 2020 16:20'	System	12 Aug 2020 21:20:50

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:00:23
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 4'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-13T18:42:06', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e41dea45-9830-41aa-8912-7c3f50b99ddc'	System	13 Aug 2020 23:42:23
User entered 'None (1)'	System	13 Aug 2020 23:42:23

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:00:23
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-13T18:42:10', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e41dea45-9830-41aa-8912-7c3f50b99ddc'	System	13 Aug 2020 23:42:23
User entered 'No (N)'	System	13 Aug 2020 23:42:23

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-13T18:42:14', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e41dea45-9830-41aa-8912-7c3f50b99ddc'	System	13 Aug 2020 23:42:23
User entered 'No (N)'	System	13 Aug 2020 23:42:23

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-13T18:42:17', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e41dea45-9830-41aa-8912-7c3f50b99ddc'	System	13 Aug 2020 23:42:23
User entered 'None (1)'	System	13 Aug 2020 23:42:23

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:00:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-13T18:42:21', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e41dea45-9830-41aa-8912-7c3f50b99ddc'	System	13 Aug 2020 23:42:23
User entered '13 Aug 2020 18:42'	System	13 Aug 2020 23:42:23

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:00:23
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:00:23
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 5'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-14T12:17:17', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '94cef9dd-5f1b-47ad-bbd2-fcf7fca56279'	System	14 Aug 2020 17:18:11
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 17:18:11

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-14T12:17:37', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '94cef9dd-5f1b-47ad-bbd2-fcf7fca56279'	System	14 Aug 2020 17:18:11
User entered 'No (N)'	System	14 Aug 2020 17:18:11

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-14T12:17:41', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '94cef9dd-5f1b-47ad-bbd2-fcf7fca56279'	System	14 Aug 2020 17:18:11
User entered 'No (N)'	System	14 Aug 2020 17:18:11

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-14T12:17:45', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '94cef9dd-5f1b-47ad-bbd2-fcf7fca56279'	System	14 Aug 2020 17:18:11
User entered 'None (1)'	System	14 Aug 2020 17:18:11

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:00:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-14T12:17:49', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '94cef9dd-5f1b-47ad-bbd2-fcf7fca56279'	System	14 Aug 2020 17:18:11
User entered '14 Aug 2020 12:17'	System	14 Aug 2020 17:18:11

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:00:23
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 6'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-15T12:14:51', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'c48d87f4-3dda-4322-b14b-fed9736c0f2e'	System	15 Aug 2020 17:15:08
User entered 'None (1)'	System	15 Aug 2020 17:15:08

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-15T12:14:54', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'c48d87f4-3dda-4322-b14b-fed9736c0f2e'	System	15 Aug 2020 17:15:08
User entered 'No (N)'	System	15 Aug 2020 17:15:08

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-15T12:14:57', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'c48d87f4-3dda-4322-b14b-fed9736c0f2e'	System	15 Aug 2020 17:15:08
User entered 'No (N)'	System	15 Aug 2020 17:15:08

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-15T12:15:01', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'c48d87f4-3dda-4322-b14b-fed9736c0f2e'	System	15 Aug 2020 17:15:08
User entered 'None (1)'	System	15 Aug 2020 17:15:08

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:00:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-15T12:15:04', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'c48d87f4-3dda-4322-b14b-fed9736c0f2e'	System	15 Aug 2020 17:15:08
User entered '15 Aug 2020 12:15'	System	15 Aug 2020 17:15:08

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:00:23
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 7'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-16T13:20:03', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '48617a27-7f6b-447c-8b8b-8b6a582745c4'	System	16 Aug 2020 18:20:20
User entered 'None (1)'	System	16 Aug 2020 18:20:20

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-16T13:20:06', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '48617a27-7f6b-447c-8b8b-8b6a582745c4'	System	16 Aug 2020 18:20:20
User entered 'No (N)'	System	16 Aug 2020 18:20:20

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-16T13:20:10', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '48617a27-7f6b-447c-8b8b-8b6a582745c4'	System	16 Aug 2020 18:20:20
User entered 'No (N)'	System	16 Aug 2020 18:20:20

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-16T13:20:13', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '48617a27-7f6b-447c-8b8b-8b6a582745c4'	System	16 Aug 2020 18:20:20
User entered 'None (1)'	System	16 Aug 2020 18:20:20

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:00:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-16T13:20:16', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '48617a27-7f6b-447c-8b8b-8b6a582745c4'	System	16 Aug 2020 18:20:20
User entered '16 Aug 2020 13:20'	System	16 Aug 2020 18:20:20

US3312006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:00:23
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T13:36:55', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'dbbe994c-a5ba-4e8e-80ee-72bdc76c7987'	System	10 Aug 2020 18:37:28
User entered 'None (0)'	System	10 Aug 2020 18:37:28

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:00:23
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T13:36:59', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'dbbe994c-a5ba-4e8e-80ee-72bdc76c7987'	System	10 Aug 2020 18:37:28
User entered 'None (0)'	System	10 Aug 2020 18:37:28

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:00:23
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T13:37:01', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'dbbe994c-a5ba-4e8e-80ee-72bdc76c7987'	System	10 Aug 2020 18:37:28
User entered 'None (0)'	System	10 Aug 2020 18:37:28

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T13:37:12', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'dbbe994c-a5ba-4e8e-80ee-72bdc76c7987'	System	10 Aug 2020 18:37:28
User entered 'None (0)'	System	10 Aug 2020 18:37:28

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:00:23
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T13:37:14', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'dbbe994c-a5ba-4e8e-80ee-72bdc76c7987'	System	10 Aug 2020 18:37:28
User entered 'None (0)'	System	10 Aug 2020 18:37:28

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:00:23
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T13:37:16', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'dbbe994c-a5ba-4e8e-80ee-72bdc76c7987'	System	10 Aug 2020 18:37:28
User entered 'None (0)'	System	10 Aug 2020 18:37:28

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T13:37:20', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'dbbe994c-a5ba-4e8e-80ee-72bdc76c7987'	System	10 Aug 2020 18:37:28
User entered 'No (N)'	System	10 Aug 2020 18:37:28

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T13:37:26', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'dbbe994c-a5ba-4e8e-80ee-72bdc76c7987'	System	10 Aug 2020 18:37:28
User entered '10 Aug 2020 13:37'	System	10 Aug 2020 18:37:28

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '10 Aug 2020 13:14'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '10 Aug 2020 15:44'	System	10 Aug 2020 18:03:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:00:23
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T19:26:44', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '62e4fd17-32e3-4fc6-96a7-eb4bd6cc0bd7'	System	11 Aug 2020 00:27:26
User entered 'None (0)'	System	11 Aug 2020 00:27:26

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:00:23
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T19:26:55', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '62e4fd17-32e3-4fc6-96a7-eb4bd6cc0bd7'	System	11 Aug 2020 00:27:26
User entered 'None (0)'	System	11 Aug 2020 00:27:26

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:00:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T19:26:58', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '62e4fd17-32e3-4fc6-96a7-eb4bd6cc0bd7'	System	11 Aug 2020 00:27:26
User entered 'None (0)'	System	11 Aug 2020 00:27:26

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T19:27:07', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '62e4fd17-32e3-4fc6-96a7-eb4bd6cc0bd7'	System	11 Aug 2020 00:27:26
User entered 'None (0)'	System	11 Aug 2020 00:27:26

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:00:23
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T19:27:08', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '62e4fd17-32e3-4fc6-96a7-eb4bd6cc0bd7'	System	11 Aug 2020 00:27:26
User entered 'None (0)'	System	11 Aug 2020 00:27:26

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:00:23
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T19:27:10', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '62e4fd17-32e3-4fc6-96a7-eb4bd6cc0bd7'	System	11 Aug 2020 00:27:26
User entered 'None (0)'	System	11 Aug 2020 00:27:26

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T19:27:17', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '62e4fd17-32e3-4fc6-96a7-eb4bd6cc0bd7'	System	11 Aug 2020 00:27:26
User entered 'No (N)'	System	11 Aug 2020 00:27:26

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-10T19:27:25', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '62e4fd17-32e3-4fc6-96a7-eb4bd6cc0bd7'	System	11 Aug 2020 00:27:26
User entered '10 Aug 2020 19:27'	System	11 Aug 2020 00:27:26

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '10 Aug 2020 16:39'	System	10 Aug 2020 18:03:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 2'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:00:23
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-11T18:28:51', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'dad60c8f-23ec-4c6b-a030-c70df30eed2e'	System	11 Aug 2020 23:29:43
User entered 'None (0)'	System	11 Aug 2020 23:29:43

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:00:23
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-11T18:28:53', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'dad60c8f-23ec-4c6b-a030-c70df30eed2e'	System	11 Aug 2020 23:29:43
User entered 'None (0)'	System	11 Aug 2020 23:29:43

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:00:23
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-11T18:28:56', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'dad60c8f-23ec-4c6b-a030-c70df30eed2e'	System	11 Aug 2020 23:29:43
User entered 'None (0)'	System	11 Aug 2020 23:29:43

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:00:23
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-11T18:28:58', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'dad60c8f-23ec-4c6b-a030-c70df30eed2e'	System	11 Aug 2020 23:29:43
User entered 'None (0)'	System	11 Aug 2020 23:29:43

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-11T18:29:01', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'dad60c8f-23ec-4c6b-a030-c70df30eed2e'	System	11 Aug 2020 23:29:43
User entered 'None (0)'	System	11 Aug 2020 23:29:43

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-11T18:29:03', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'dad60c8f-23ec-4c6b-a030-c70df30eed2e'	System	11 Aug 2020 23:29:43
User entered 'None (0)'	System	11 Aug 2020 23:29:43

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-11T18:29:08', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'dad60c8f-23ec-4c6b-a030-c70df30eed2e'	System	11 Aug 2020 23:29:43
User entered 'No (N)'	System	11 Aug 2020 23:29:43

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:00:23
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-11T18:29:17', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'dad60c8f-23ec-4c6b-a030-c70df30eed2e'	System	11 Aug 2020 23:29:43
User entered '11 Aug 2020 18:29'	System	11 Aug 2020 23:29:43

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:00:23
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 3'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:00:23
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-12T16:21:05', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '297bd4b4-633f-4f39-a92b-5027313e770c'	System	12 Aug 2020 21:22:26
User entered 'None (0)'	System	12 Aug 2020 21:22:26

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:00:23
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-12T16:21:07', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '297bd4b4-633f-4f39-a92b-5027313e770c'	System	12 Aug 2020 21:22:26
User entered 'None (0)'	System	12 Aug 2020 21:22:26

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:00:23
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-12T16:21:10', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '297bd4b4-633f-4f39-a92b-5027313e770c'	System	12 Aug 2020 21:22:26
User entered 'None (0)'	System	12 Aug 2020 21:22:26

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:00:23
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-12T16:21:12', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '297bd4b4-633f-4f39-a92b-5027313e770c'	System	12 Aug 2020 21:22:26
User entered 'None (0)'	System	12 Aug 2020 21:22:26

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:00:23
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-12T16:21:14', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '297bd4b4-633f-4f39-a92b-5027313e770c'	System	12 Aug 2020 21:22:26
User entered 'None (0)'	System	12 Aug 2020 21:22:26

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-12T16:21:16', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '297bd4b4-633f-4f39-a92b-5027313e770c'	System	12 Aug 2020 21:22:26
User entered 'None (0)'	System	12 Aug 2020 21:22:26

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:00:23
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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-12T16:21:40', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '297bd4b4-633f-4f39-a92b-5027313e770c'	System	12 Aug 2020 21:22:26
User entered 'No (N)'	System	12 Aug 2020 21:22:26

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:23

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-12T16:22:22', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '297bd4b4-633f-4f39-a92b-5027313e770c'	System	12 Aug 2020 21:22:26
User entered '12 Aug 2020 16:22'	System	12 Aug 2020 21:22:26

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 4'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:00:23
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-13T18:42:43', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9a811c34-1275-45db-8d72-9b6a4a3df838'	System	13 Aug 2020 23:43:44
User entered 'None (0)'	System	13 Aug 2020 23:43:44

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:00:23
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-13T18:42:46', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9a811c34-1275-45db-8d72-9b6a4a3df838'	System	13 Aug 2020 23:43:44
User entered 'None (0)'	System	13 Aug 2020 23:43:44

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:00:23
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-13T18:42:49', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9a811c34-1275-45db-8d72-9b6a4a3df838'	System	13 Aug 2020 23:43:44
User entered 'None (0)'	System	13 Aug 2020 23:43:44

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:00:23
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-13T18:42:51', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9a811c34-1275-45db-8d72-9b6a4a3df838'	System	13 Aug 2020 23:43:44
User entered 'None (0)'	System	13 Aug 2020 23:43:44

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-13T18:42:54', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9a811c34-1275-45db-8d72-9b6a4a3df838'	System	13 Aug 2020 23:43:44
User entered 'None (0)'	System	13 Aug 2020 23:43:44

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:00:23
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-13T18:42:57', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9a811c34-1275-45db-8d72-9b6a4a3df838'	System	13 Aug 2020 23:43:44
User entered 'None (0)'	System	13 Aug 2020 23:43:44

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-13T18:43:34', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9a811c34-1275-45db-8d72-9b6a4a3df838'	System	13 Aug 2020 23:43:44
User entered 'No (N)'	System	13 Aug 2020 23:43:44

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:23

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-13T18:43:40', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9a811c34-1275-45db-8d72-9b6a4a3df838'	System	13 Aug 2020 23:43:44
User entered '13 Aug 2020 18:43'	System	13 Aug 2020 23:43:44

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 5'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:00:23
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-14T12:17:52', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a47bc294-afa3-499d-9e73-f19e65f79dd8'	System	14 Aug 2020 17:18:11
User entered 'None (0)'	System	14 Aug 2020 17:18:11

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:00:23
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-14T12:17:54', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a47bc294-afa3-499d-9e73-f19e65f79dd8'	System	14 Aug 2020 17:18:11
User entered 'None (0)'	System	14 Aug 2020 17:18:11

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:00:23
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-14T12:17:56', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a47bc294-afa3-499d-9e73-f19e65f79dd8'	System	14 Aug 2020 17:18:11
User entered 'None (0)'	System	14 Aug 2020 17:18:11

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:00:23
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-14T12:17:57', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a47bc294-afa3-499d-9e73-f19e65f79dd8'	System	14 Aug 2020 17:18:11
User entered 'None (0)'	System	14 Aug 2020 17:18:11

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:00:23
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-14T12:17:59', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a47bc294-afa3-499d-9e73-f19e65f79dd8'	System	14 Aug 2020 17:18:11
User entered 'None (0)'	System	14 Aug 2020 17:18:11

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-14T12:18:01', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a47bc294-afa3-499d-9e73-f19e65f79dd8'	System	14 Aug 2020 17:18:11
User entered 'None (0)'	System	14 Aug 2020 17:18:11

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-14T12:18:04', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a47bc294-afa3-499d-9e73-f19e65f79dd8'	System	14 Aug 2020 17:18:11
User entered 'No (N)'	System	14 Aug 2020 17:18:11

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:23

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-14T12:18:07', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a47bc294-afa3-499d-9e73-f19e65f79dd8'	System	14 Aug 2020 17:18:11
User entered '14 Aug 2020 12:18'	System	14 Aug 2020 17:18:11

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:00:23
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 6'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-15T12:15:08', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e02ad480-d134-48c1-b4f9-a7b17b62b144'	System	15 Aug 2020 17:15:31
User entered 'None (0)'	System	15 Aug 2020 17:15:31

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:00:23
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-15T12:15:11', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e02ad480-d134-48c1-b4f9-a7b17b62b144'	System	15 Aug 2020 17:15:31
User entered 'None (0)'	System	15 Aug 2020 17:15:31

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:00:23
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-15T12:15:13', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e02ad480-d134-48c1-b4f9-a7b17b62b144'	System	15 Aug 2020 17:15:31
User entered 'None (0)'	System	15 Aug 2020 17:15:31

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:00:23
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-15T12:15:16', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e02ad480-d134-48c1-b4f9-a7b17b62b144'	System	15 Aug 2020 17:15:31
User entered 'None (0)'	System	15 Aug 2020 17:15:31

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:00:23
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-15T12:15:18', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e02ad480-d134-48c1-b4f9-a7b17b62b144'	System	15 Aug 2020 17:15:31
User entered 'None (0)'	System	15 Aug 2020 17:15:31

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:00:23
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-15T12:15:19', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e02ad480-d134-48c1-b4f9-a7b17b62b144'	System	15 Aug 2020 17:15:31
User entered 'None (0)'	System	15 Aug 2020 17:15:31

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:00:23
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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-15T12:15:22', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e02ad480-d134-48c1-b4f9-a7b17b62b144'	System	15 Aug 2020 17:15:31
User entered 'No (N)'	System	15 Aug 2020 17:15:31

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:23

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-15T12:15:27', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e02ad480-d134-48c1-b4f9-a7b17b62b144'	System	15 Aug 2020 17:15:31
User entered '15 Aug 2020 12:15'	System	15 Aug 2020 17:15:31

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:00:23
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 7'	System	10 Aug 2020 18:03:17

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:00:23
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-16T13:20:19', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '1af03fa5-0efc-4151-8690-e8a0afd54adc'	System	16 Aug 2020 18:20:40
User entered 'None (0)'	System	16 Aug 2020 18:20:40

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:00:23
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-16T13:20:21', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '1af03fa5-0efc-4151-8690-e8a0afd54adc'	System	16 Aug 2020 18:20:40
User entered 'None (0)'	System	16 Aug 2020 18:20:40

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:00:23
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-16T13:20:24', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '1af03fa5-0efc-4151-8690-e8a0afd54adc'	System	16 Aug 2020 18:20:40
User entered 'None (0)'	System	16 Aug 2020 18:20:40

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-16T13:20:26', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '1af03fa5-0efc-4151-8690-e8a0afd54adc'	System	16 Aug 2020 18:20:40
User entered 'None (0)'	System	16 Aug 2020 18:20:40

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:00:23
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-16T13:20:27', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '1af03fa5-0efc-4151-8690-e8a0afd54adc'	System	16 Aug 2020 18:20:40
User entered 'None (0)'	System	16 Aug 2020 18:20:40

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-16T13:20:29', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '1af03fa5-0efc-4151-8690-e8a0afd54adc'	System	16 Aug 2020 18:20:40
User entered 'None (0)'	System	16 Aug 2020 18:20:40

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-16T13:20:34', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '1af03fa5-0efc-4151-8690-e8a0afd54adc'	System	16 Aug 2020 18:20:40
User entered 'No (N)'	System	16 Aug 2020 18:20:40

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:23

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-08-16T13:20:37', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '1af03fa5-0efc-4151-8690-e8a0afd54adc'	System	16 Aug 2020 18:20:40
User entered '16 Aug 2020 13:20'	System	16 Aug 2020 18:20:40

US3312006
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:00:23
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 18:03:17

US3312006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 18:03:17

US3312006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:23

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	17 Aug 2020 18:46:31

US3312006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '17 Aug 2020'	Kelly Moen (b) (4) (b) (4)	17 Aug 2020 18:46:31

US3312006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:23

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Contact Made (CONTACT MADE)'	Kelly Moen (b) (4) (b) (4)	17 Aug 2020 18:46:31

US3312006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:23

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered empty.	Kelly Moen (b) (4) (b) (4)	17 Aug 2020 18:46:31

US3312006

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:23

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	17 Aug 2020 18:46:38

US3312006

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:23

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User entered '1'	System	17 Aug 2020 18:46:38

US3312006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:23

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 20:07:18

US3312006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '24 Aug 2020'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 20:07:18

US3312006
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:00:23
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Contact Made (CONTACT MADE)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 20:07:18

US3312006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:23

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered empty.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 20:07:18

US3312006

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:23

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 20:07:22

US3312006
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:00:23
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:51:20
User entered '1'	System	24 Aug 2020 20:07:22

US3312006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:23

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	31 Aug 2020 22:32:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '31 Aug 2020'	Kelly Moen (b) (4) (b) (4)	31 Aug 2020 22:32:18

US3312006
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:00:23
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Contact Made (CONTACT MADE)'	Kelly Moen (b) (4) (b) (4)	31 Aug 2020 22:32:18

US3312006
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:00:23
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered empty.	Kelly Moen (b) (4) (b) (4)	31 Aug 2020 22:32:18

US3312006
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:00:23

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	31 Aug 2020 22:32:24

US3312006
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:00:23
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered '1'	System	31 Aug 2020 22:32:24

US3312006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:23

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	07 Sep 2020 15:39:12

US3312006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:23

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '7 Sep 2020'	Christa Estrada (b) (4) (b) (4)	07 Sep 2020 15:39:12

US3312006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4) (b) (4)	07 Sep 2020 15:39:12

US3312006
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:00:23
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered 'VISIT2'	System	07 Sep 2020 15:39:12

US3312006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:23

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:44:22

US3312006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:23

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:44:22

FDA-CBER-2022-1614-0852501

US3312006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:23

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '07 Sep 2020'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:44:22

US3312006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '09:17'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:44:22

US3312006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:23

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered '07 Sep 2020 09:17'	System	11 Sep 2020 15:44:22

US3312006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:23

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '98.0' F	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:44:22

US3312006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:23

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:44:22

US3312006
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:00:23
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered empty.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:44:22

US3312006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:23

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '56' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	27 Jan 2021 23:00:04
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	11 Sep 2020 15:44:36
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	11 Sep 2020 15:44:36
User entered '51' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:44:36
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	11 Sep 2020 15:44:22
User entered '16'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:44:22

US3312006
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:00:23
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered 'bpm'	System	11 Sep 2020 15:44:22

US3312006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:23

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User closed query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	11 Sep 2020 15:44:36
Query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	11 Sep 2020 15:44:36
User entered '16' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:44:36
User opened query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	11 Sep 2020 15:44:22
User entered '51'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:44:22

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered 'breaths/min'	System	11 Sep 2020 15:44:22

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '146'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:44:22

FDA-CBER-2022-1614-0852512

US3312006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:23

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered 'mmHg'	System	11 Sep 2020 15:44:22

US3312006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:23

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '90'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:44:22

US3312006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered 'mmHg'	System	11 Sep 2020 15:44:22

US3312006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:23

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:44:22

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:23

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:44:22

US3312006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:23

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '07 Sep 2020'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:44:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '11:07'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:44:22

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US3312006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:23

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered '07 Sep 2020 11:07'	System	11 Sep 2020 15:44:22

US3312006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:23

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '98.1' F	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:44:22

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:00:23

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:44:22

US3312006
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:00:23
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered empty.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:44:22

US3312006
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:00:23
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '51' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	27 Jan 2021 23:00:04
User entered '49'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:44:22

US3312006
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:00:23
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered 'bpm'	System	11 Sep 2020 15:44:22

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '14'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:44:22

US3312006
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:00:23
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered 'breaths/min'	System	11 Sep 2020 15:44:22

US3312006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:23

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '133' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	27 Jan 2021 23:00:04
User entered '146'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:44:22

US3312006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:23

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered 'mmHg'	System	11 Sep 2020 15:44:22

US3312006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:23

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '70' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	27 Jan 2021 23:00:04
User entered '94'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:44:22

US3312006
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:00:23
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered 'mmHg'	System	11 Sep 2020 15:44:22

Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:00:23

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:50:04

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Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:00:23

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '07 Sep 2020'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:50:04

US3312006
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:00:23
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	07 Sep 2020 15:39:28

US3312006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:23

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered empty.	Christa Estrada (b) (4) (b) (4)	07 Sep 2020 15:39:28

US3312006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:23

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered empty.	Christa Estrada (b) (4) (b) (4)	07 Sep 2020 15:39:28

US3312006
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:00:23
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered 'MRNA-1273 OR PLACEBO'	System	07 Sep 2020 15:39:28

US3312006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '7 Sep 2020'	Christa Estrada (b) (4) (b) (4)	07 Sep 2020 15:39:28

US3312006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User closed query 'Per CDM: Per protocol, On Day 1 and Day 29 vital sign measurements will be collected once before IP injection and at least 30 minutes after IP injection. Please reconcile' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 14:17:59
Query 'Per CDM: Per protocol, On Day 1 and Day 29 vital sign measurements will be collected once before IP injection and at least 30 minutes after IP injection. Please reconcile' answered with 'na' (Site from DM).	Karol Moore (b) (4) (b) (4)	20 Oct 2020 21:49:31
User opened query 'Per CDM: Per protocol, On Day 1 and Day 29 vital sign measurements will be collected once before IP injection and at least 30 minutes after IP injection. Please reconcile' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 20:19:50
User entered '10:36'	Christa Estrada (b) (4) (b) (4)	07 Sep 2020 15:39:28

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:00:23

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered '7 Sep 2020 10:36'	System	07 Sep 2020 15:39:28

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:15
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4)	07 Sep 2020 15:39:28
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:23

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered 'ONCE'	System	07 Sep 2020 15:39:28

US3312006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered 'INTRAMUSCULAR'	System	07 Sep 2020 15:39:28

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:23

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:50:15

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '07 Sep 2020'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:50:15

US3312006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '10:01'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:50:15

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered '07 Sep 2020 10:01'	System	11 Sep 2020 15:50:15

FDA-CBER-2022-1614-0852547

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '07 Sep 2020'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:50:26

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US3312006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:23

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:50:26

US3312006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:23

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:50:26

US3312006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '09:46'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:50:26

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:23

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered '07 Sep 2020 09:46'	System	11 Sep 2020 15:50:26

US3312006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:23

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:50:26

US3312006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:23

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:50:26

US3312006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered empty.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:50:26

US3312006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:23

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered empty.	System	11 Sep 2020 15:50:26

US3312006
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:00:23

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	07 Sep 2020 15:39:35

US3312006
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:00:23
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered '1'	System	07 Sep 2020 15:39:35

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	07 Sep 2020 15:39:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T11:08:13', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '4efd2b71-1108-4ef1-b560-b200c17a2a17'	System	07 Sep 2020 16:08:32
User entered 'Yes (Y)'	System	07 Sep 2020 16:08:32

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T11:08:20', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '4efd2b71-1108-4ef1-b560-b200c17a2a17'	System	07 Sep 2020 16:08:32
User entered '98.1'	System	07 Sep 2020 16:08:32

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T11:08:24', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '4efd2b71-1108-4ef1-b560-b200c17a2a17'	System	07 Sep 2020 16:08:32
User entered 'No (N)'	System	07 Sep 2020 16:08:32

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:00:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T11:08:31', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '4efd2b71-1108-4ef1-b560-b200c17a2a17'	System	07 Sep 2020 16:08:32
User entered '07 Sep 2020 11:08'	System	07 Sep 2020 16:08:32

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '07 Sep 2020 10:56'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '07 Sep 2020 13:26'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	07 Sep 2020 15:39:28
User entered 'Day 1, after vaccination (at home)'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:00:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T14:43:32', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '23289dee-8f7f-4a91-ba19-d140dbf2a956'	System	07 Sep 2020 19:43:54
User entered 'Yes (Y)'	System	07 Sep 2020 19:43:54

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T14:43:40', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '23289dee-8f7f-4a91-ba19-d140dbf2a956'	System	07 Sep 2020 19:43:54
User entered '98.0'	System	07 Sep 2020 19:43:54

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T14:43:44', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '23289dee-8f7f-4a91-ba19-d140dbf2a956'	System	07 Sep 2020 19:43:54
User entered 'No (N)'	System	07 Sep 2020 19:43:54

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T14:43:49', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '23289dee-8f7f-4a91-ba19-d140dbf2a956'	System	07 Sep 2020 19:43:54
User entered '07 Sep 2020 14:43'	System	07 Sep 2020 19:43:54

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '07 Sep 2020 14:21'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '08 Sep 2020 11:59'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	07 Sep 2020 15:39:28
User entered 'Day 2'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:00:23
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-08T15:02:08', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e0129cb6-c29c-45ed-b382-45775b9e30ec'	System	08 Sep 2020 20:02:30
User entered 'Yes (Y)'	System	08 Sep 2020 20:02:30

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:00:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-08T15:02:14', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e0129cb6-c29c-45ed-b382-45775b9e30ec'	System	08 Sep 2020 20:02:30
User entered '97.6'	System	08 Sep 2020 20:02:30

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-08T15:02:19', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e0129cb6-c29c-45ed-b382-45775b9e30ec'	System	08 Sep 2020 20:02:30
User entered 'No (N)'	System	08 Sep 2020 20:02:30

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:00:23

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-08T15:02:26', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e0129cb6-c29c-45ed-b382-45775b9e30ec'	System	08 Sep 2020 20:02:30
User entered '08 Sep 2020 15:02'	System	08 Sep 2020 20:02:30

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	07 Sep 2020 15:39:28
User entered 'Day 3'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-09T17:11:40', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'd948a3d2-236d-4b59-ab9a-83a8af445554'	System	09 Sep 2020 22:11:54
User entered 'Yes (Y)'	System	09 Sep 2020 22:11:54

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:00:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-09T17:11:45', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'd948a3d2-236d-4b59-ab9a-83a8af445554'	System	09 Sep 2020 22:11:54
User entered '98.2'	System	09 Sep 2020 22:11:54

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-09T17:11:49', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'd948a3d2-236d-4b59-ab9a-83a8af445554'	System	09 Sep 2020 22:11:54
User entered 'No (N)'	System	09 Sep 2020 22:11:54

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:00:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-09T17:11:52', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'd948a3d2-236d-4b59-ab9a-83a8af445554'	System	09 Sep 2020 22:11:54
User entered '09 Sep 2020 17:11'	System	09 Sep 2020 22:11:54

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	07 Sep 2020 15:39:28
User entered 'Day 4'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:00:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-10T19:48:23', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9a8a6728-755b-4e03-8654-e9194e971a80'	System	11 Sep 2020 00:48:38
User entered 'Yes (Y)'	System	11 Sep 2020 00:48:38

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:00:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-10T19:48:30', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9a8a6728-755b-4e03-8654-e9194e971a80'	System	11 Sep 2020 00:48:38
User entered '97.4'	System	11 Sep 2020 00:48:38

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-10T19:48:34', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9a8a6728-755b-4e03-8654-e9194e971a80'	System	11 Sep 2020 00:48:38
User entered 'No (N)'	System	11 Sep 2020 00:48:38

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:23

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-10T19:48:37', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9a8a6728-755b-4e03-8654-e9194e971a80'	System	11 Sep 2020 00:48:38
User entered '10 Sep 2020 19:48'	System	11 Sep 2020 00:48:38

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '10 Sep 2020 12:00'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '11 Sep 2020 11:59'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	07 Sep 2020 15:39:28
User entered 'Day 5'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:00:23
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-11T12:09:56', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '0247759a-fa2d-47b3-82b3-9c8f290415f5'	System	11 Sep 2020 17:10:18
User entered 'Yes (Y)'	System	11 Sep 2020 17:10:18

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:00:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-11T12:10:01', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '0247759a-fa2d-47b3-82b3-9c8f290415f5'	System	11 Sep 2020 17:10:18
User entered '98.2'	System	11 Sep 2020 17:10:18

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-11T12:10:05', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '0247759a-fa2d-47b3-82b3-9c8f290415f5'	System	11 Sep 2020 17:10:18
User entered 'No (N)'	System	11 Sep 2020 17:10:18

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:00:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-11T12:10:13', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '0247759a-fa2d-47b3-82b3-9c8f290415f5'	System	11 Sep 2020 17:10:18
User entered '11 Sep 2020 12:10'	System	11 Sep 2020 17:10:18

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '11 Sep 2020 12:00'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:00:23
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '12 Sep 2020 11:59'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	07 Sep 2020 15:39:28
User entered 'Day 6'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:00:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-12T12:28:13', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '8f8780b7-ced9-4e7f-a8ba-a2cb6fc004e9'	System	12 Sep 2020 17:28:27
User entered 'Yes (Y)'	System	12 Sep 2020 17:28:27

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:00:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-12T12:28:17', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '8f8780b7-ced9-4e7f-a8ba-a2cb6fc004e9'	System	12 Sep 2020 17:28:27
User entered '97.1'	System	12 Sep 2020 17:28:27

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-12T12:28:21', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '8f8780b7-ced9-4e7f-a8ba-a2cb6fc004e9'	System	12 Sep 2020 17:28:27
User entered 'No (N)'	System	12 Sep 2020 17:28:27

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:00:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-12T12:28:25', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '8f8780b7-ced9-4e7f-a8ba-a2cb6fc004e9'	System	12 Sep 2020 17:28:27
User entered '12 Sep 2020 12:28'	System	12 Sep 2020 17:28:27

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '12 Sep 2020 12:00'	System	07 Sep 2020 15:39:28

FDA-CBER-2022-1614-0852606

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '13 Sep 2020 11:59'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	07 Sep 2020 15:39:28
User entered 'Day 7'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:00:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-13T13:27:07', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9d391bcb-d523-46bb-8e99-e40c2e6f134d'	System	13 Sep 2020 18:27:22
User entered 'Yes (Y)'	System	13 Sep 2020 18:27:22

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:00:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-13T13:27:11', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9d391bcb-d523-46bb-8e99-e40c2e6f134d'	System	13 Sep 2020 18:27:22
User entered '98.6'	System	13 Sep 2020 18:27:22

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-13T13:27:15', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9d391bcb-d523-46bb-8e99-e40c2e6f134d'	System	13 Sep 2020 18:27:22
User entered 'No (N)'	System	13 Sep 2020 18:27:22

US3312006
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:00:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-13T13:27:18', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9d391bcb-d523-46bb-8e99-e40c2e6f134d'	System	13 Sep 2020 18:27:22
User entered '13 Sep 2020 13:27'	System	13 Sep 2020 18:27:22

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '13 Sep 2020 12:00'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '14 Sep 2020 11:59'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	07 Sep 2020 15:39:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T11:08:37', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a3f7fa53-9b1a-4255-8673-16ed0d6f490e'	System	07 Sep 2020 16:08:53
User entered 'None (1)'	System	07 Sep 2020 16:08:53

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T11:08:41', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a3f7fa53-9b1a-4255-8673-16ed0d6f490e'	System	07 Sep 2020 16:08:53
User entered 'No (N)'	System	07 Sep 2020 16:08:53

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:00:23
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T11:08:44', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a3f7fa53-9b1a-4255-8673-16ed0d6f490e'	System	07 Sep 2020 16:08:53
User entered 'No (N)'	System	07 Sep 2020 16:08:53

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T11:08:48', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a3f7fa53-9b1a-4255-8673-16ed0d6f490e'	System	07 Sep 2020 16:08:53
User entered 'None (1)'	System	07 Sep 2020 16:08:53

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:00:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T11:08:51', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a3f7fa53-9b1a-4255-8673-16ed0d6f490e'	System	07 Sep 2020 16:08:53
User entered '07 Sep 2020 11:08'	System	07 Sep 2020 16:08:53

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:00:23
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '07 Sep 2020 10:56'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '07 Sep 2020 13:26'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	07 Sep 2020 15:39:28
User entered 'Day 1, after vaccination (at home)'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T14:44:03', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '1b9a6a7d-5ac5-4094-9afa-6c67bbab946c'	System	07 Sep 2020 19:44:23
User entered 'None (1)'	System	07 Sep 2020 19:44:23

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T14:44:10', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '1b9a6a7d-5ac5-4094-9afa-6c67bbab946c'	System	07 Sep 2020 19:44:23
User entered 'No (N)'	System	07 Sep 2020 19:44:23

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:00:23
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T14:44:13', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '1b9a6a7d-5ac5-4094-9afa-6c67bbab946c'	System	07 Sep 2020 19:44:23
User entered 'No (N)'	System	07 Sep 2020 19:44:23

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T14:44:17', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '1b9a6a7d-5ac5-4094-9afa-6c67bbab946c'	System	07 Sep 2020 19:44:23
User entered 'None (1)'	System	07 Sep 2020 19:44:23

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T14:44:20', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '1b9a6a7d-5ac5-4094-9afa-6c67bbab946c'	System	07 Sep 2020 19:44:23
User entered '07 Sep 2020 14:44'	System	07 Sep 2020 19:44:23

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '07 Sep 2020 14:21'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:00:23
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '08 Sep 2020 11:59'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	07 Sep 2020 15:39:28
User entered 'Day 2'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-08T15:02:54', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e24edfdc-17cf-41a7-9fc7-b34c7745622c'	System	08 Sep 2020 20:03:12
User entered 'Does not interfere with activity (2)'	System	08 Sep 2020 20:03:12

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-08T15:02:57', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e24edfdc-17cf-41a7-9fc7-b34c7745622c'	System	08 Sep 2020 20:03:12
User entered 'No (N)'	System	08 Sep 2020 20:03:12

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:00:23
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-08T15:03:01', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e24edfdc-17cf-41a7-9fc7-b34c7745622c'	System	08 Sep 2020 20:03:12
User entered 'No (N)'	System	08 Sep 2020 20:03:12

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-08T15:03:07', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e24edfdc-17cf-41a7-9fc7-b34c7745622c'	System	08 Sep 2020 20:03:12
User entered 'None (1)'	System	08 Sep 2020 20:03:12

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:00:23

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-08T15:03:10', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'e24edfdc-17cf-41a7-9fc7-b34c7745622c'	System	08 Sep 2020 20:03:12
User entered '08 Sep 2020 15:03'	System	08 Sep 2020 20:03:12

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:00:23
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	07 Sep 2020 15:39:28
User entered 'Day 3'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-09T17:12:01', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'f6a92712-8c65-4bc7-a414-3bd35674a865'	System	09 Sep 2020 22:12:20
User entered 'None (1)'	System	09 Sep 2020 22:12:20

FDA-CBER-2022-1614-0852640

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-09T17:12:04', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'f6a92712-8c65-4bc7-a414-3bd35674a865'	System	09 Sep 2020 22:12:20
User entered 'No (N)'	System	09 Sep 2020 22:12:20

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-09T17:12:07', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'f6a92712-8c65-4bc7-a414-3bd35674a865'	System	09 Sep 2020 22:12:20
User entered 'No (N)'	System	09 Sep 2020 22:12:20

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-09T17:12:10', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'f6a92712-8c65-4bc7-a414-3bd35674a865'	System	09 Sep 2020 22:12:20
User entered 'None (1)'	System	09 Sep 2020 22:12:20

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:23

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-09T17:12:15', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'f6a92712-8c65-4bc7-a414-3bd35674a865'	System	09 Sep 2020 22:12:20
User entered '09 Sep 2020 17:12'	System	09 Sep 2020 22:12:20

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 15:39:28

FDA-CBER-2022-1614-0852645

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 15:39:28

FDA-CBER-2022-1614-0852646

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	07 Sep 2020 15:39:28
User entered 'Day 4'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-10T19:48:57', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '242b989c-f103-4878-a4df-0b72b9311416'	System	11 Sep 2020 00:49:20
User entered 'None (1)'	System	11 Sep 2020 00:49:20

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-10T19:48:54', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '242b989c-f103-4878-a4df-0b72b9311416'	System	11 Sep 2020 00:49:20
User entered 'No (N)'	System	11 Sep 2020 00:49:20

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:00:23
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-10T19:49:01', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '242b989c-f103-4878-a4df-0b72b9311416'	System	11 Sep 2020 00:49:20
User entered 'No (N)'	System	11 Sep 2020 00:49:20

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-10T19:49:06', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '242b989c-f103-4878-a4df-0b72b9311416'	System	11 Sep 2020 00:49:20
User entered 'None (1)'	System	11 Sep 2020 00:49:20

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:00:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-10T19:49:14', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '242b989c-f103-4878-a4df-0b72b9311416'	System	11 Sep 2020 00:49:20
User entered '10 Sep 2020 19:49'	System	11 Sep 2020 00:49:20

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:00:23
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '10 Sep 2020 12:00'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '11 Sep 2020 11:59'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	07 Sep 2020 15:39:28
User entered 'Day 5'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-11T12:10:23', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'ac28f094-4fce-4900-b3ec-7b04dcda0c15'	System	11 Sep 2020 17:10:42
User entered 'None (1)'	System	11 Sep 2020 17:10:42

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-11T12:10:26', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'ac28f094-4fce-4900-b3ec-7b04dcda0c15'	System	11 Sep 2020 17:10:42
User entered 'No (N)'	System	11 Sep 2020 17:10:42

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-11T12:10:30', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'ac28f094-4fce-4900-b3ec-7b04dcda0c15'	System	11 Sep 2020 17:10:42
User entered 'No (N)'	System	11 Sep 2020 17:10:42

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-11T12:10:34', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'ac28f094-4fce-4900-b3ec-7b04dcda0c15'	System	11 Sep 2020 17:10:42
User entered 'None (1)'	System	11 Sep 2020 17:10:42

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:00:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-11T12:10:37', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'ac28f094-4fce-4900-b3ec-7b04dcda0c15'	System	11 Sep 2020 17:10:42
User entered '11 Sep 2020 12:10'	System	11 Sep 2020 17:10:42

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:00:23
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '11 Sep 2020 12:00'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:00:23
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '12 Sep 2020 11:59'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	07 Sep 2020 15:39:28
User entered 'Day 6'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-12T12:28:33', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '433499f6-2ace-4443-99ee-9a5e6924c895'	System	12 Sep 2020 17:29:38
User entered 'None (1)'	System	12 Sep 2020 17:29:38

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-12T12:28:35', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '433499f6-2ace-4443-99ee-9a5e6924c895'	System	12 Sep 2020 17:29:38
User entered 'No (N)'	System	12 Sep 2020 17:29:38

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-12T12:28:40', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '433499f6-2ace-4443-99ee-9a5e6924c895'	System	12 Sep 2020 17:29:38
User entered 'No (N)'	System	12 Sep 2020 17:29:38

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-12T12:29:07', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '433499f6-2ace-4443-99ee-9a5e6924c895'	System	12 Sep 2020 17:29:38
User entered 'None (1)'	System	12 Sep 2020 17:29:38

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:00:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-12T12:29:37', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '433499f6-2ace-4443-99ee-9a5e6924c895'	System	12 Sep 2020 17:29:38
User entered '12 Sep 2020 12:29'	System	12 Sep 2020 17:29:38

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '12 Sep 2020 12:00'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '13 Sep 2020 11:59'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	07 Sep 2020 15:39:28
User entered 'Day 7'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-13T13:27:23', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '52fa121b-1ab9-411c-ae1d-98f7f70d56e2'	System	13 Sep 2020 18:27:37
User entered 'None (1)'	System	13 Sep 2020 18:27:37

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-13T13:27:26', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '52fa121b-1ab9-411c-ae1d-98f7f70d56e2'	System	13 Sep 2020 18:27:37
User entered 'No (N)'	System	13 Sep 2020 18:27:37

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-13T13:27:29', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '52fa121b-1ab9-411c-ae1d-98f7f70d56e2'	System	13 Sep 2020 18:27:37
User entered 'No (N)'	System	13 Sep 2020 18:27:37

US3312006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-13T13:27:32', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '52fa121b-1ab9-411c-ae1d-98f7f70d56e2'	System	13 Sep 2020 18:27:37
User entered 'None (1)'	System	13 Sep 2020 18:27:37

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:00:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-13T13:27:36', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '52fa121b-1ab9-411c-ae1d-98f7f70d56e2'	System	13 Sep 2020 18:27:37
User entered '13 Sep 2020 13:27'	System	13 Sep 2020 18:27:37

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:00:23
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '13 Sep 2020 12:00'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:00:23
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '14 Sep 2020 11:59'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	07 Sep 2020 15:39:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:00:23
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T11:08:57', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'd651c5ed-ccfc-4100-9ae7-4ee2da3c3efa'	System	07 Sep 2020 16:09:22
User entered 'None (0)'	System	07 Sep 2020 16:09:22

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:00:23
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T11:09:00', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'd651c5ed-ccfc-4100-9ae7-4ee2da3c3efa'	System	07 Sep 2020 16:09:22
User entered 'None (0)'	System	07 Sep 2020 16:09:22

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:00:23
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T11:09:04', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'd651c5ed-ccfc-4100-9ae7-4ee2da3c3efa'	System	07 Sep 2020 16:09:22
User entered 'None (0)'	System	07 Sep 2020 16:09:22

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T11:09:07', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'd651c5ed-ccfc-4100-9ae7-4ee2da3c3efa'	System	07 Sep 2020 16:09:22
User entered 'None (0)'	System	07 Sep 2020 16:09:22

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T11:09:09', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'd651c5ed-ccfc-4100-9ae7-4ee2da3c3efa'	System	07 Sep 2020 16:09:22
User entered 'None (0)'	System	07 Sep 2020 16:09:22

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:00:23
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T11:09:10', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'd651c5ed-ccfc-4100-9ae7-4ee2da3c3efa'	System	07 Sep 2020 16:09:22
User entered 'None (0)'	System	07 Sep 2020 16:09:22

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T11:09:15', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'd651c5ed-ccfc-4100-9ae7-4ee2da3c3efa'	System	07 Sep 2020 16:09:22
User entered 'No (N)'	System	07 Sep 2020 16:09:22

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T11:09:20', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'd651c5ed-ccfc-4100-9ae7-4ee2da3c3efa'	System	07 Sep 2020 16:09:22
User entered '07 Sep 2020 11:09'	System	07 Sep 2020 16:09:22

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '07 Sep 2020 10:56'	System	07 Sep 2020 15:39:28

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '07 Sep 2020 13:26'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	07 Sep 2020 15:39:28
User entered 'Day 1, after vaccination (at home)'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T14:44:26', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9ebf1dd2-176b-4a53-8b53-a71a21783681'	System	07 Sep 2020 19:44:46
User entered 'None (0)'	System	07 Sep 2020 19:44:46

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:00:23
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T14:44:28', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9ebf1dd2-176b-4a53-8b53-a71a21783681'	System	07 Sep 2020 19:44:46
User entered 'None (0)'	System	07 Sep 2020 19:44:46

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:00:23
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T14:44:29', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9ebf1dd2-176b-4a53-8b53-a71a21783681'	System	07 Sep 2020 19:44:46
User entered 'None (0)'	System	07 Sep 2020 19:44:46

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T14:44:31', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9ebf1dd2-176b-4a53-8b53-a71a21783681'	System	07 Sep 2020 19:44:46
User entered 'None (0)'	System	07 Sep 2020 19:44:46

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T14:44:32', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9ebf1dd2-176b-4a53-8b53-a71a21783681'	System	07 Sep 2020 19:44:46
User entered 'None (0)'	System	07 Sep 2020 19:44:46

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:00:23
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T14:44:34', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9ebf1dd2-176b-4a53-8b53-a71a21783681'	System	07 Sep 2020 19:44:46
User entered 'None (0)'	System	07 Sep 2020 19:44:46

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T14:44:36', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9ebf1dd2-176b-4a53-8b53-a71a21783681'	System	07 Sep 2020 19:44:46
User entered 'No (N)'	System	07 Sep 2020 19:44:46

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-07T14:44:44', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '9ebf1dd2-176b-4a53-8b53-a71a21783681'	System	07 Sep 2020 19:44:46
User entered '07 Sep 2020 14:44'	System	07 Sep 2020 19:44:46

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '07 Sep 2020 14:21'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '08 Sep 2020 11:59'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	07 Sep 2020 15:39:28
User entered 'Day 2'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:00:23
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-08T15:03:16', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a7328000-c1dd-4187-888c-57bf15be3084'	System	08 Sep 2020 20:03:39
User entered 'None (0)'	System	08 Sep 2020 20:03:39

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:00:23
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-08T15:03:19', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a7328000-c1dd-4187-888c-57bf15be3084'	System	08 Sep 2020 20:03:39
User entered 'None (0)'	System	08 Sep 2020 20:03:39

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:00:23
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-08T15:03:22', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a7328000-c1dd-4187-888c-57bf15be3084'	System	08 Sep 2020 20:03:39
User entered 'None (0)'	System	08 Sep 2020 20:03:39

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-08T15:03:26', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a7328000-c1dd-4187-888c-57bf15be3084'	System	08 Sep 2020 20:03:39
User entered 'None (0)'	System	08 Sep 2020 20:03:39

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:00:23
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-08T15:03:28', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a7328000-c1dd-4187-888c-57bf15be3084'	System	08 Sep 2020 20:03:39
User entered 'None (0)'	System	08 Sep 2020 20:03:39

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-08T15:03:30', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a7328000-c1dd-4187-888c-57bf15be3084'	System	08 Sep 2020 20:03:39
User entered 'None (0)'	System	08 Sep 2020 20:03:39

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-08T15:03:33', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a7328000-c1dd-4187-888c-57bf15be3084'	System	08 Sep 2020 20:03:39
User entered 'No (N)'	System	08 Sep 2020 20:03:39

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:23

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-08T15:03:36', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a7328000-c1dd-4187-888c-57bf15be3084'	System	08 Sep 2020 20:03:39
User entered '08 Sep 2020 15:03'	System	08 Sep 2020 20:03:39

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	07 Sep 2020 15:39:28
User entered 'Day 3'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-09T17:12:20', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '80cf3974-51d9-45c1-be59-37e0d6d689e3'	System	09 Sep 2020 22:12:43
User entered 'None (0)'	System	09 Sep 2020 22:12:43

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:00:23
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-09T17:12:22', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '80cf3974-51d9-45c1-be59-37e0d6d689e3'	System	09 Sep 2020 22:12:43
User entered 'None (0)'	System	09 Sep 2020 22:12:43

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-09T17:12:25', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '80cf3974-51d9-45c1-be59-37e0d6d689e3'	System	09 Sep 2020 22:12:43
User entered 'None (0)'	System	09 Sep 2020 22:12:43

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-09T17:12:27', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '80cf3974-51d9-45c1-be59-37e0d6d689e3'	System	09 Sep 2020 22:12:43
User entered 'None (0)'	System	09 Sep 2020 22:12:43

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-09T17:12:30', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '80cf3974-51d9-45c1-be59-37e0d6d689e3'	System	09 Sep 2020 22:12:43
User entered 'None (0)'	System	09 Sep 2020 22:12:43

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-09T17:12:32', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '80cf3974-51d9-45c1-be59-37e0d6d689e3'	System	09 Sep 2020 22:12:43
User entered 'None (0)'	System	09 Sep 2020 22:12:43

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-09T17:12:36', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '80cf3974-51d9-45c1-be59-37e0d6d689e3'	System	09 Sep 2020 22:12:43
User entered 'No (N)'	System	09 Sep 2020 22:12:43

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:23

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-09T17:12:41', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '80cf3974-51d9-45c1-be59-37e0d6d689e3'	System	09 Sep 2020 22:12:43
User entered '09 Sep 2020 17:12'	System	09 Sep 2020 22:12:43

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	07 Sep 2020 15:39:28
User entered 'Day 4'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:00:23
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-10T19:49:19', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'f87d5446-cb6e-4ef1-aa77-b28187af6ef6'	System	11 Sep 2020 00:49:40
User entered 'None (0)'	System	11 Sep 2020 00:49:40

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:00:23
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-10T19:49:21', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'f87d5446-cb6e-4ef1-aa77-b28187af6ef6'	System	11 Sep 2020 00:49:40
User entered 'None (0)'	System	11 Sep 2020 00:49:40

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:00:23
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-10T19:49:24', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'f87d5446-cb6e-4ef1-aa77-b28187af6ef6'	System	11 Sep 2020 00:49:40
User entered 'None (0)'	System	11 Sep 2020 00:49:40

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:00:23
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-10T19:49:26', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'f87d5446-cb6e-4ef1-aa77-b28187af6ef6'	System	11 Sep 2020 00:49:40
User entered 'None (0)'	System	11 Sep 2020 00:49:40

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:00:23
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-10T19:49:28', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'f87d5446-cb6e-4ef1-aa77-b28187af6ef6'	System	11 Sep 2020 00:49:40
User entered 'None (0)'	System	11 Sep 2020 00:49:40

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:00:23
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-10T19:49:29', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'f87d5446-cb6e-4ef1-aa77-b28187af6ef6'	System	11 Sep 2020 00:49:40
User entered 'None (0)'	System	11 Sep 2020 00:49:40

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-10T19:49:32', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'f87d5446-cb6e-4ef1-aa77-b28187af6ef6'	System	11 Sep 2020 00:49:40
User entered 'No (N)'	System	11 Sep 2020 00:49:40

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:23

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-10T19:49:38', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'f87d5446-cb6e-4ef1-aa77-b28187af6ef6'	System	11 Sep 2020 00:49:40
User entered '10 Sep 2020 19:49'	System	11 Sep 2020 00:49:40

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '10 Sep 2020 12:00'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '11 Sep 2020 11:59'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	07 Sep 2020 15:39:28
User entered 'Day 5'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:00:23
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-11T12:10:41', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a38151fb-3edd-4900-8a66-ad10acfe4089'	System	11 Sep 2020 17:11:11
User entered 'None (0)'	System	11 Sep 2020 17:11:11

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:00:23
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-11T12:10:42', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a38151fb-3edd-4900-8a66-ad10acfe4089'	System	11 Sep 2020 17:11:11
User entered 'None (0)'	System	11 Sep 2020 17:11:11

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-11T12:10:44', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a38151fb-3edd-4900-8a66-ad10acfe4089'	System	11 Sep 2020 17:11:11
User entered 'None (0)'	System	11 Sep 2020 17:11:11

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:00:23
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-11T12:10:45', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a38151fb-3edd-4900-8a66-ad10acfe4089'	System	11 Sep 2020 17:11:11
User entered 'None (0)'	System	11 Sep 2020 17:11:11

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:00:23
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-11T12:10:47', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a38151fb-3edd-4900-8a66-ad10acfe4089'	System	11 Sep 2020 17:11:11
User entered 'None (0)'	System	11 Sep 2020 17:11:11

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-11T12:10:51', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a38151fb-3edd-4900-8a66-ad10acfe4089'	System	11 Sep 2020 17:11:11
User entered 'None (0)'	System	11 Sep 2020 17:11:11

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-11T12:10:53', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a38151fb-3edd-4900-8a66-ad10acfe4089'	System	11 Sep 2020 17:11:11
User entered 'No (N)'	System	11 Sep 2020 17:11:11

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:23

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-11T12:10:58', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'a38151fb-3edd-4900-8a66-ad10acfe4089'	System	11 Sep 2020 17:11:11
User entered '11 Sep 2020 12:10'	System	11 Sep 2020 17:11:11

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '11 Sep 2020 12:00'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '12 Sep 2020 11:59'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	07 Sep 2020 15:39:28
User entered 'Day 6'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:00:23
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-12T12:29:42', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'd127ee73-2c32-474f-8363-feec6c300d4f'	System	12 Sep 2020 17:31:28
User entered 'None (0)'	System	12 Sep 2020 17:31:28

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:00:23
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-12T12:29:45', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'd127ee73-2c32-474f-8363-feec6c300d4f'	System	12 Sep 2020 17:31:28
User entered 'None (0)'	System	12 Sep 2020 17:31:28

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:00:23
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-12T12:29:47', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'd127ee73-2c32-474f-8363-feec6c300d4f'	System	12 Sep 2020 17:31:28
User entered 'None (0)'	System	12 Sep 2020 17:31:28

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-12T12:29:52', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'd127ee73-2c32-474f-8363-feec6c300d4f'	System	12 Sep 2020 17:31:28
User entered 'None (0)'	System	12 Sep 2020 17:31:28

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-12T12:29:54', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'd127ee73-2c32-474f-8363-feec6c300d4f'	System	12 Sep 2020 17:31:28
User entered 'None (0)'	System	12 Sep 2020 17:31:28

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-12T12:29:56', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'd127ee73-2c32-474f-8363-feec6c300d4f'	System	12 Sep 2020 17:31:28
User entered 'None (0)'	System	12 Sep 2020 17:31:28

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-12T12:31:20', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'd127ee73-2c32-474f-8363-feec6c300d4f'	System	12 Sep 2020 17:31:28
User entered 'No (N)'	System	12 Sep 2020 17:31:28

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:23

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-12T12:31:27', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'd127ee73-2c32-474f-8363-feec6c300d4f'	System	12 Sep 2020 17:31:28
User entered '12 Sep 2020 12:31'	System	12 Sep 2020 17:31:28

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:00:23
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '12 Sep 2020 12:00'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '13 Sep 2020 11:59'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	07 Sep 2020 15:39:28
User entered 'Day 7'	System	07 Sep 2020 15:39:28

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:00:23
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-13T13:27:53', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '110ee646-c833-4396-8567-dc509ad0dff8'	System	13 Sep 2020 18:29:15
User entered 'None (0)'	System	13 Sep 2020 18:29:15

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:00:23
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-13T13:28:28', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '110ee646-c833-4396-8567-dc509ad0dff8'	System	13 Sep 2020 18:29:15
User entered 'None (0)'	System	13 Sep 2020 18:29:15

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-13T13:28:31', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '110ee646-c833-4396-8567-dc509ad0dff8'	System	13 Sep 2020 18:29:15
User entered 'None (0)'	System	13 Sep 2020 18:29:15

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-13T13:28:34', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '110ee646-c833-4396-8567-dc509ad0dff8'	System	13 Sep 2020 18:29:15
User entered 'None (0)'	System	13 Sep 2020 18:29:15

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-13T13:28:37', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '110ee646-c833-4396-8567-dc509ad0dff8'	System	13 Sep 2020 18:29:15
User entered 'None (0)'	System	13 Sep 2020 18:29:15

US3312006
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:00:23
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-13T13:28:40', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '110ee646-c833-4396-8567-dc509ad0dff8'	System	13 Sep 2020 18:29:15
User entered 'None (0)'	System	13 Sep 2020 18:29:15

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:23

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 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-13T13:28:48', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '110ee646-c833-4396-8567-dc509ad0dff8'	System	13 Sep 2020 18:29:15
User entered 'No (N)'	System	13 Sep 2020 18:29:15

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:23

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-09-13T13:28:52', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '110ee646-c833-4396-8567-dc509ad0dff8'	System	13 Sep 2020 18:29:15
User entered '13 Sep 2020 13:28'	System	13 Sep 2020 18:29:15

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '13 Sep 2020 12:00'	System	07 Sep 2020 15:39:28

US3312006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
User entered '14 Sep 2020 11:59'	System	07 Sep 2020 15:39:28

US3312006
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:00:23

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	15 Sep 2020 13:32:24

US3312006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '14 Sep 2020'	Karol Moore (b) (4) (b) (4)	15 Sep 2020 13:32:24

Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:00:23
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	15 Sep 2020 13:32:24

US3312006
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:00:23
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered empty.	Karol Moore (b) (4) (b) (4)	15 Sep 2020 13:32:24

US3312006
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:00:23

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	15 Sep 2020 13:32:30

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered '1'	System	15 Sep 2020 13:32:30

FDA-CBER-2022-1614-0852772

US3312006
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:00:23

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	22 Sep 2020 17:41:31

US3312006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '21 Sep 2020'	Karol Moore (b) (4) (b) (4)	22 Sep 2020 17:41:31

US3312006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:23

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	22 Sep 2020 17:41:31

US3312006
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:00:23
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered empty.	Karol Moore (b) (4) (b) (4)	22 Sep 2020 17:41:31

US3312006
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:00:23

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	22 Sep 2020 17:41:18

US3312006
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:00:23
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered '1'	System	22 Sep 2020 17:41:18

US3312006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:23

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Monica Atwood (b) (4) (b) (4)	07 Oct 2020 19:12:40

US3312006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '28 Sep 2020'	Monica Atwood (b) (4) (b) (4)	07 Oct 2020 19:12:40

US3312006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:23

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Contact Made (CONTACT MADE)'	Monica Atwood (b) (4) (b) (4)	07 Oct 2020 19:12:40

US3312006
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:00:23
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered empty.	Monica Atwood (b) (4) (b) (4)	07 Oct 2020 19:12:40

US3312006
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:00:23

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	Monica Atwood (b) (4) (b) (4)	07 Oct 2020 19:12:44

US3312006
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:00:23
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered '1'	System	07 Oct 2020 19:12:44

US3312006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:23

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 16:48:12

US3312006
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:00:23

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:15
User entered '5 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 16:48:12

US3312006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:15
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	09 Oct 2020 16:48:12

US3312006
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:00:23
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered 'VISIT3'	System	09 Oct 2020 16:48:12

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 16:48:53

FDA-CBER-2022-1614-0852789

US3312006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:23

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '5 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 16:48:53

US3312006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '09:02'	(b) (4), (b) (6)	09 Oct 2020 16:48:53

US3312006
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:00:23

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered '5 Oct 2020 09:02'	System	09 Oct 2020 16:48:53

US3312006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:23

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:15
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 17:55:26
User entered '99' F	(b) (4), (b) (6)	09 Oct 2020 16:48:53

US3312006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:23

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:15
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Oct 2020 16:48:53

US3312006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:23

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:15
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:48:53

US3312006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:23

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '55'	(b) (4), (b) (6)	09 Oct 2020 16:48:53

US3312006
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:00:23
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered 'bpm'	System	09 Oct 2020 16:48:53

US3312006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:23

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '14'	(b) (4), (b) (6)	09 Oct 2020 16:48:53

US3312006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:23

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered 'breaths/min'	System	09 Oct 2020 16:48:53

US3312006
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:00:23

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:15
User entered '97'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:48:53

US3312006
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:00:23
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered 'mmHg'	System	09 Oct 2020 16:48:53

US3312006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:23

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:15
User entered '77'	(b) (4), (b) (6)	09 Oct 2020 16:48:53

US3312006
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:00:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered 'mmHg'	System	09 Oct 2020 16:48:53

US3312006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:23

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16

US3312006
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:00:23

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16

US3312006

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:23

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:48:59

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:15
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 16:48:59

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 16:49:11

US3312006

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:23

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:15
User entered '5 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 16:49:11

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:15
User entered '09:22'	(b) (4), (b) (6)	09 Oct 2020 16:49:11

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered '5 Oct 2020 09:22'	System	09 Oct 2020 16:49:11

FDA-CBER-2022-1614-0852811

US3312006
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:00:23

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 16:49:18

US3312006
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:00:23
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered '1'	System	09 Oct 2020 16:49:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 64'	System	10 Aug 2020 18:03:17

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-10-10T08:46:44', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '6d62b124-6d21-407f-9648-f1768cf9daac'	System	10 Oct 2020 13:47:07
User entered 'No (N)'	System	10 Oct 2020 13:47:07

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-10-10T08:46:50', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '6d62b124-6d21-407f-9648-f1768cf9daac'	System	10 Oct 2020 13:47:07
User entered 'No (N)'	System	10 Oct 2020 13:47:07

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-10-10T08:47:04', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '6d62b124-6d21-407f-9648-f1768cf9daac'	System	10 Oct 2020 13:47:07
User entered '10 Oct 2020 08:47:04'	System	10 Oct 2020 13:47:07

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 18:03:17

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 18:03:17

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 71'	System	10 Aug 2020 18:03:17

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-10-17T10:21:52', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'dbffbe70-fb2d-4595-81d4-ab336f220622'	System	17 Oct 2020 15:22:20
User entered 'No (N)'	System	17 Oct 2020 15:22:20

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-10-17T10:21:58', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'dbffbe70-fb2d-4595-81d4-ab336f220622'	System	17 Oct 2020 15:22:20
User entered 'No (N)'	System	17 Oct 2020 15:22:20

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-10-17T10:22:17', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'dbffbe70-fb2d-4595-81d4-ab336f220622'	System	17 Oct 2020 15:22:20
User entered '17 Oct 2020 10:22:17'	System	17 Oct 2020 15:22:20

US3312006
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 18:03:17

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 18:03:17

US3312006
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 78'	System	10 Aug 2020 18:03:17

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-10-24T06:52:20', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'b6b04863-de89-419b-8f03-42009477f382'	System	24 Oct 2020 11:52:39
User entered 'No (N)'	System	24 Oct 2020 11:52:39

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-10-24T06:52:31', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'b6b04863-de89-419b-8f03-42009477f382'	System	24 Oct 2020 11:52:39
User entered 'No (N)'	System	24 Oct 2020 11:52:39

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-10-24T06:52:37', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'b6b04863-de89-419b-8f03-42009477f382'	System	24 Oct 2020 11:52:39
User entered '24 Oct 2020 06:52:37'	System	24 Oct 2020 11:52:39

US3312006
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 18:03:17

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 18:03:17

US3312006
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 92'	System	10 Aug 2020 18:03:17

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-11-07T06:07:02', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '7facb6ff-a9f7-436c-a961-c266f6b569be'	System	07 Nov 2020 12:07:31
User entered 'No (N)'	System	07 Nov 2020 12:07:31

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-11-07T06:07:11', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '7facb6ff-a9f7-436c-a961-c266f6b569be'	System	07 Nov 2020 12:07:31
User entered 'No (N)'	System	07 Nov 2020 12:07:31

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-11-07T06:07:29', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '7facb6ff-a9f7-436c-a961-c266f6b569be'	System	07 Nov 2020 12:07:31
User entered '07 Nov 2020 06:07:29'	System	07 Nov 2020 12:07:31

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 18:03:17

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 18:03:17

US3312006
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered 'Day 99'	System	10 Aug 2020 18:03:17

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-11-14T06:07:44', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '5af2a906-e1bd-4218-ab4e-695d177f4f2d'	System	14 Nov 2020 12:07:58
User entered 'No (N)'	System	14 Nov 2020 12:07:58

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-11-14T06:07:51', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '5af2a906-e1bd-4218-ab4e-695d177f4f2d'	System	14 Nov 2020 12:07:58
User entered 'No (N)'	System	14 Nov 2020 12:07:58

US3312006
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-11-14T06:07:56', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '5af2a906-e1bd-4218-ab4e-695d177f4f2d'	System	14 Nov 2020 12:07:58
User entered '14 Nov 2020 06:07:56'	System	14 Nov 2020 12:07:58

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 18:03:17

US3312006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:50
Data entry locked.	System	10 Aug 2020 18:03:17
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 18:03:17

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 17:16:42

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-11-20T13:47:40', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '5f08dc55-43ee-42f2-94ac-4f5236ae7eb8'	System	20 Nov 2020 19:48:02
User entered 'No (N)'	System	20 Nov 2020 19:48:02

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Have you been exposed to someone with 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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-11-20T13:47:54', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '5f08dc55-43ee-42f2-94ac-4f5236ae7eb8'	System	20 Nov 2020 19:48:02
User entered 'No (N)'	System	20 Nov 2020 19:48:02

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-11-20T13:47:58', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '5f08dc55-43ee-42f2-94ac-4f5236ae7eb8'	System	20 Nov 2020 19:48:02
User entered '20 Nov 2020 13:47:58'	System	20 Nov 2020 19:48:02

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 17:16:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 17:16:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 17:16:42

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-11-25T06:39:33', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'ffecd3b2-9144-47d0-946d-49181733e861'	System	25 Nov 2020 12:39:52
User entered 'No (N)'	System	25 Nov 2020 12:39:52

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23

Have you been exposed to someone with 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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-11-25T06:39:42', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'ffecd3b2-9144-47d0-946d-49181733e861'	System	25 Nov 2020 12:39:52
User entered 'No (N)'	System	25 Nov 2020 12:39:52

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-11-25T06:39:48', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'ffecd3b2-9144-47d0-946d-49181733e861'	System	25 Nov 2020 12:39:52
User entered '25 Nov 2020 06:39:48'	System	25 Nov 2020 12:39:52

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 17:16:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 17:16:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 17:16:42

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-12-02T06:35:06', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '28d0a265-4dfe-4ecb-8bed-872a5c2d3eb4'	System	02 Dec 2020 12:35:28
User entered 'No (N)'	System	02 Dec 2020 12:35:28

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Have you been exposed to someone with 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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-12-02T06:35:18', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '28d0a265-4dfe-4ecb-8bed-872a5c2d3eb4'	System	02 Dec 2020 12:35:28
User entered 'No (N)'	System	02 Dec 2020 12:35:28

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-12-02T06:35:24', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '28d0a265-4dfe-4ecb-8bed-872a5c2d3eb4'	System	02 Dec 2020 12:35:28
User entered '02 Dec 2020 06:35:24'	System	02 Dec 2020 12:35:28

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 17:16:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 17:16:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 17:16:42

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-12-09T16:37:14', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '5109c99d-8155-4289-a0bb-f8524c75d71a'	System	09 Dec 2020 22:37:40
User entered 'No (N)'	System	09 Dec 2020 22:37:40

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Have you been exposed to someone with 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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-12-09T16:37:32', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '5109c99d-8155-4289-a0bb-f8524c75d71a'	System	09 Dec 2020 22:37:40
User entered 'No (N)'	System	09 Dec 2020 22:37:40

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-12-09T16:37:37', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '5109c99d-8155-4289-a0bb-f8524c75d71a'	System	09 Dec 2020 22:37:40
User entered '09 Dec 2020 16:37:37'	System	09 Dec 2020 22:37:40

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 17:16:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 17:16:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 17:16:42

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-12-16T06:28:35', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '3fcbc27e-be2e-40d1-8b65-c660783f1b25'	System	16 Dec 2020 12:28:51
User entered 'No (N)'	System	16 Dec 2020 12:28:51

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Have you been exposed to someone with 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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-12-16T06:28:42', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '3fcbc27e-be2e-40d1-8b65-c660783f1b25'	System	16 Dec 2020 12:28:51
User entered 'No (N)'	System	16 Dec 2020 12:28:51

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-12-16T06:28:49', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '3fcbc27e-be2e-40d1-8b65-c660783f1b25'	System	16 Dec 2020 12:28:51
User entered '16 Dec 2020 06:28:49'	System	16 Dec 2020 12:28:51

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 17:16:42

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 17:16:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 17:16:42

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-12-23T07:08:58', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '91360f5a-52f5-425e-a65b-a897294656cb'	System	23 Dec 2020 13:09:21
User entered 'No (N)'	System	23 Dec 2020 13:09:21

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23

Have you been exposed to someone with 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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-12-23T07:09:14', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '91360f5a-52f5-425e-a65b-a897294656cb'	System	23 Dec 2020 13:09:21
User entered 'No (N)'	System	23 Dec 2020 13:09:21

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-12-23T07:09:18', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '91360f5a-52f5-425e-a65b-a897294656cb'	System	23 Dec 2020 13:09:21
User entered '23 Dec 2020 07:09:18'	System	23 Dec 2020 13:09:21

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 17:16:42

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 17:16:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 17:16:42

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-12-30T16:32:19', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'de1662a3-2a65-4ca6-a4ed-7e94c494d4f3'	System	30 Dec 2020 22:32:51
User entered 'No (N)'	System	30 Dec 2020 22:32:51

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US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Have you been exposed to someone with 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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-12-30T16:32:43', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'de1662a3-2a65-4ca6-a4ed-7e94c494d4f3'	System	30 Dec 2020 22:32:51
User entered 'No (N)'	System	30 Dec 2020 22:32:51

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2020-12-30T16:32:49', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'de1662a3-2a65-4ca6-a4ed-7e94c494d4f3'	System	30 Dec 2020 22:32:51
User entered '30 Dec 2020 16:32:49'	System	30 Dec 2020 22:32:51

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 17:16:42

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 17:16:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 17:16:42

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-01-08T12:00:44', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'cf5d0b9c-15b2-4bc5-b405-f056be1c1ab1'	System	08 Jan 2021 18:01:02
User entered 'No (N)'	System	08 Jan 2021 18:01:02

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Have you been exposed to someone with 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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-01-08T12:00:50', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'cf5d0b9c-15b2-4bc5-b405-f056be1c1ab1'	System	08 Jan 2021 18:01:02
User entered 'No (N)'	System	08 Jan 2021 18:01:02

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-01-08T12:00:55', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'cf5d0b9c-15b2-4bc5-b405-f056be1c1ab1'	System	08 Jan 2021 18:01:02
User entered '08 Jan 2021 12:00:55'	System	08 Jan 2021 18:01:02

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 17:16:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 17:16:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 17:16:42

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US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-01-13T06:38:15', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '34683ac3-9d96-4499-826b-c98ed38703c6'	System	13 Jan 2021 12:38:32
User entered 'No (N)'	System	13 Jan 2021 12:38:32

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Have you been exposed to someone with 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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-01-13T06:38:26', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '34683ac3-9d96-4499-826b-c98ed38703c6'	System	13 Jan 2021 12:38:32
User entered 'No (N)'	System	13 Jan 2021 12:38:32

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-01-13T06:38:30', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '34683ac3-9d96-4499-826b-c98ed38703c6'	System	13 Jan 2021 12:38:32
User entered '13 Jan 2021 06:38:30'	System	13 Jan 2021 12:38:32

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 17:16:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 17:16:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 17:16:42

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-01-20T06:37:24', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '249d8579-6c39-4946-8363-5e8ced017584'	System	20 Jan 2021 12:37:42
User entered 'No (N)'	System	20 Jan 2021 12:37:42

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Have you been exposed to someone with 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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-01-20T06:37:32', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '249d8579-6c39-4946-8363-5e8ced017584'	System	20 Jan 2021 12:37:42
User entered 'No (N)'	System	20 Jan 2021 12:37:42

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-01-20T06:37:37', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '249d8579-6c39-4946-8363-5e8ced017584'	System	20 Jan 2021 12:37:42
User entered '20 Jan 2021 06:37:37'	System	20 Jan 2021 12:37:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 17:16:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 17:16:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 17:16:42

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-01-27T06:08:27', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '27e439f1-0cae-4a42-b146-9e8502b1e896'	System	27 Jan 2021 12:08:39
User entered 'No (N)'	System	27 Jan 2021 12:08:39

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Have you been exposed to someone with 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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-01-27T06:08:33', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '27e439f1-0cae-4a42-b146-9e8502b1e896'	System	27 Jan 2021 12:08:39
User entered 'No (N)'	System	27 Jan 2021 12:08:39

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-01-27T06:08:36', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '27e439f1-0cae-4a42-b146-9e8502b1e896'	System	27 Jan 2021 12:08:39
User entered '27 Jan 2021 06:08:36'	System	27 Jan 2021 12:08:39

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 17:16:42

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 17:16:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 17:16:42

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-02-03T06:37:55', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'f38f904a-87b9-4182-8b0c-c521a29a8cc7'	System	03 Feb 2021 12:38:11
User entered 'No (N)'	System	03 Feb 2021 12:38:11

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Have you been exposed to someone with 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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-02-03T06:38:03', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'f38f904a-87b9-4182-8b0c-c521a29a8cc7'	System	03 Feb 2021 12:38:11
User entered 'No (N)'	System	03 Feb 2021 12:38:11

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-02-03T06:38:06', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'f38f904a-87b9-4182-8b0c-c521a29a8cc7'	System	03 Feb 2021 12:38:11
User entered '03 Feb 2021 06:38:06'	System	03 Feb 2021 12:38:11

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 17:16:42

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 17:16:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 17:16:42

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-02-10T06:23:13', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '7cfd3fa8-2b60-4f28-818d-bd1dd9e443c4'	System	10 Feb 2021 12:23:23
User entered 'No (N)'	System	10 Feb 2021 12:23:23

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Have you been exposed to someone with 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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-02-10T06:23:17', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '7cfd3fa8-2b60-4f28-818d-bd1dd9e443c4'	System	10 Feb 2021 12:23:23
User entered 'No (N)'	System	10 Feb 2021 12:23:23

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-02-10T06:23:21', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '7cfd3fa8-2b60-4f28-818d-bd1dd9e443c4'	System	10 Feb 2021 12:23:23
User entered '10 Feb 2021 06:23:21'	System	10 Feb 2021 12:23:23

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 17:16:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 17:16:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 17:16:42

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-02-17T05:42:21', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'eee02d26-d5ee-46ba-a384-4f0921bcd4ff'	System	17 Feb 2021 11:42:45
User entered 'No (N)'	System	17 Feb 2021 11:42:45

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23

Have you been exposed to someone with 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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-02-17T05:42:29', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'eee02d26-d5ee-46ba-a384-4f0921bcd4ff'	System	17 Feb 2021 11:42:45
User entered 'No (N)'	System	17 Feb 2021 11:42:45

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-02-17T05:42:41', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'eee02d26-d5ee-46ba-a384-4f0921bcd4ff'	System	17 Feb 2021 11:42:45
User entered '17 Feb 2021 05:42:41'	System	17 Feb 2021 11:42:45

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 17:16:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 17:16:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 17:16:42

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-02-24T06:20:25-06:00', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '393c0688-4779-4945-97d2-3b933d5673ac'	System	24 Feb 2021 12:20:39
User entered 'No (N)'	System	24 Feb 2021 12:20:39

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Have you been exposed to someone with 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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-02-24T06:20:33-06:00', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '393c0688-4779-4945-97d2-3b933d5673ac'	System	24 Feb 2021 12:20:39
User entered 'No (N)'	System	24 Feb 2021 12:20:39

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-02-24T06:20:37-06:00', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '393c0688-4779-4945-97d2-3b933d5673ac'	System	24 Feb 2021 12:20:39
User entered '24 Feb 2021 12:20:37'	System	24 Feb 2021 12:20:39

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 17:16:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 17:16:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 17:16:42

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-03-03T05:51:55-06:00', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '1f779bd4-69f2-4a44-8ca7-04d518ef2484'	System	03 Mar 2021 11:52:36
User entered 'No (N)'	System	03 Mar 2021 11:52:36

US3312006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:23

Have you been exposed to someone with 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)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-03-03T05:52:03-06:00', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '1f779bd4-69f2-4a44-8ca7-04d518ef2484'	System	03 Mar 2021 11:52:36
User entered 'No (N)'	System	03 Mar 2021 11:52:36

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-03-03T05:52:32-06:00', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: '1f779bd4-69f2-4a44-8ca7-04d518ef2484'	System	03 Mar 2021 11:52:36
User entered '03 Mar 2021 05:52:32'	System	03 Mar 2021 11:52:36

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 17:16:42

US3312006
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:00:23
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:16:42
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 17:16:42

US3312006

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:00:23

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-02-28T17:03:21-06:00', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'ac4f4629-05ed-4659-a840-ba9c9363a651'	System	28 Feb 2021 23:09:34
User entered 'No (N)'	System	28 Feb 2021 23:09:34

US3312006

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:00:23

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F466263-D9DF-4509-83CE-233FB876A531)', Time: '2021-02-28T17:03:47-06:00', User OID: 'PatientReportedOutcome (US3312006)', ODM File OID: 'ac4f4629-05ed-4659-a840-ba9c9363a651'	System	28 Feb 2021 23:09:34
User entered '28 Feb 2021 17:03:47'	System	28 Feb 2021 23:09:34

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	03 Nov 2020 16:58:30

US3312006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
	(b) (4)	
User entered '02 Nov 2020'	Karol Moore (b) (4)	03 Nov 2020 16:58:30
	(b) (4)	

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	03 Nov 2020 16:58:30

FDA-CBER-2022-1614-0852944

US3312006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:23

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered empty.	Karol Moore (b) (4) (b) (4)	03 Nov 2020 16:58:30

US3312006
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:00:23

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	03 Nov 2020 16:58:34

US3312006
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:00:23
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:16
User entered '1'	System	03 Nov 2020 16:58:34

US3312006

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:23

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 13:53:47

US3312006

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered '07 Dec 2020'	(b) (4), (b) (6)	08 Dec 2020 13:53:47

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:53:47

FDA-CBER-2022-1614-0852950

US3312006

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:23

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 13:53:47

US3312006

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:23

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 13:53:51

US3312006
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:00:23
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:26
User entered '1'	System	08 Dec 2020 13:53:51

US3312006
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:00:23

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 14:32:21

US3312006

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered '04 Jan 2021'	(b) (4), (b) (6)	05 Jan 2021 14:32:21

US3312006

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:23

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:32:21

US3312006

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:23

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 14:32:21

US3312006
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:00:23

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 14:32:11

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:26
User entered '1'	System	05 Jan 2021 14:32:11

FDA-CBER-2022-1614-0852959

US3312006
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:00:23

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 15:18:37

US3312006

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered '01 Feb 2021'	(b) (4), (b) (6)	02 Feb 2021 15:18:37

US3312006
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:00:23
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 15:18:37

US3312006

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:23

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:26
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 15:18:37

US3312006

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:23

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'No (N)' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	02 Apr 2021 21:09:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 15:18:40

US3312006

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:23

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:26
User entered empty.	System	02 Apr 2021 21:09:54
User entered '1'	System	02 Feb 2021 15:18:40

US3312006

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

Form: Visit Date

Generated On: 09 Jun 2021 17:00:23

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 18:51:10

US3312006

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

Form: Visit Date

Generated On: 09 Jun 2021 17:00:23

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered '21 Jan 2021'	(b) (4), (b) (6)	26 Jan 2021 18:51:10

US3312006

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

Form: Visit Date

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Jan 2021 18:51:10

US3312006
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:00:23
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered 'UNBLND_DECIDE'	System	26 Jan 2021 18:51:10

US3312006

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

Form: Unblinding

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:51:26

US3312006

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

Form: Unblinding

Generated On: 09 Jun 2021 17:00:23

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:05:26

US3312006

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

Form: Unblinding

Generated On: 09 Jun 2021 17:00:23

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 18:51:26

US3312006

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

Form: Unblinding

Generated On: 09 Jun 2021 17:00:23

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:05:26

US3312006

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

Form: Unblinding

Generated On: 09 Jun 2021 17:00:23

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:51:26

US3312006

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

Form: Unblinding

Generated On: 09 Jun 2021 17:00:23

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:51:26

US3312006

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

Form: Unblinding

Generated On: 09 Jun 2021 17:00:23

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:51:26

US3312006

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

Form: Unblinding

Generated On: 09 Jun 2021 17:00:23

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:51:26

US3312006

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

Form: Unblinding

Generated On: 09 Jun 2021 17:00:23

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:51:26

US3312006

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

Form: Unblinding

Generated On: 09 Jun 2021 17:00:23

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered empty.	System	26 Jan 2021 18:51:26

US3312006
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:00:23
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered empty.	System	26 Jan 2021 18:51:26

US3312006
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:00:23
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:51:34

US3312006

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:23

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:51:34

US3312006

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered '09:06'	(b) (4), (b) (6)	26 Jan 2021 18:51:34

US3312006

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:23

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered '21 Jan 2021 09:06'	System	26 Jan 2021 18:51:34

US3312006

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:00:23

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 18:51:42

US3312006

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:00:23

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered '21 Jan 2021'	(b) (4), (b) (6)	26 Jan 2021 18:51:42

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered '09:05'	(b) (4), (b) (6)	26 Jan 2021 18:51:42

FDA-CBER-2022-1614-0852987

US3312006

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:00:23

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered '21 Jan 2021 09:05'	System	26 Jan 2021 18:51:42

US3312006

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:00:23

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:04:25

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55

FDA-CBER-2022-1614-0852990

US3312006
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:00:23
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User closed query 'Per MM, Please confirm whether this was an one time occurrence. If ongoing consider updating term to underlying medical diagnosis.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 11:49:57
Query 'Per MM, Please confirm whether this was an one time occurrence. If ongoing consider updating term to underlying medical diagnosis.' answered with 'confirm situational occurrence. not medial history. correct as entered.' (Site from DM).	Karol Moore (b) (4) (b) (4)	03 Nov 2020 17:04:52
User closed query 'Per MM, please review and confirm if treatment was given and if so, add to CM page and update, as appropriate .' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:24:15
Query 'Per MM, please review and confirm if treatment was given and if so, add to CM page and update, as appropriate .' answered with 'no treatment given' (Site from DM).	Karol Moore (b) (4) (b) (4)	20 Oct 2020 21:53:35
User opened query 'Per MM, Please confirm whether this was an one time occurrence. If ongoing consider updating term to underlying medical diagnosis.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 13:03:39
User opened query 'Per MM, please review and confirm if treatment was given and if so, add to CM page and update, as appropriate .' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 13:03:31
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure systolic increased, LLT: Blood pressure systolic increased - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:20:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:20:41
Data point term sent to Coder	System	14 Aug 2020 18:13:06
User entered 'Elevated blood (systolic) pressure'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:00:23

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:14
User closed query 'Per CDM: Response is required. Please provide.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 21:50:13
Query 'Per CDM: Response is required. Please provide.' answered with 'updated' (Site from DM).	Karol Moore (b) (4)	20 Oct 2020 21:50:39
User entered 'No (N)'	Karol Moore (b) (4)	20 Oct 2020 21:50:18
User opened query 'Per CDM: Response is required. Please provide.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 12:25:01
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 03:19:13

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 17:45:33
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	07 Sep 2020 15:39:28
User entered '10 Aug 2020'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User entered '13:27'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered '10 Aug 2020 13:27'	System	14 Aug 2020 18:13:05

FDA-CBER-2022-1614-0852997

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	03 Nov 2020 17:00:36
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	03 Nov 2020 17:05:20
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	03 Nov 2020 17:05:20
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	03 Nov 2020 17:00:36
User entered '07 Sep 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	03 Nov 2020 17:00:36
User entered empty.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Nov 2020 17:05:11
User entered '11:07' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	03 Nov 2020 17:05:11
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Nov 2020 17:00:36
User entered empty.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered '07 Sep 2020 11:07'	System	03 Nov 2020 17:05:11
User entered empty.	System	14 Aug 2020 18:13:05

US3312006
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:00:23
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User entered 'Grade 3/Severe (Grade 3/Severe)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:00:23
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User entered empty.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User entered empty.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User entered empty.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User entered empty.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	17 Aug 2020 16:13:48
User entered 'Related (RELATED)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User entered 'Related (RELATED)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	17 Aug 2020 16:13:48
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User entered 'None (NONE)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User entered '1'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User entered '0'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	03 Nov 2020 17:05:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:14
User entered empty.	Karol Moore (b) (4)	14 Aug 2020 18:13:05

US3312006
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:00:23
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:14
User entered empty.	Karol Moore (b) (4) (b) (4)	14 Aug 2020 18:13:05

US3312006
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:00:23
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: User entered '0'	System	21 Aug 2020 03:19:16
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 03:19:13

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager: User entered '0'	System	21 Aug 2020 03:19:16
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 03:19:13

US3312006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:23

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 03:19:13

US3312006
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:00:23
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:18:51
User entered 'USA-US300-2021-mRNA-1273-P301000022'	System	05 Apr 2021 13:18:46
User entered 'New'	(b) (4), (b) (6)	05 Apr 2021 13:18:46

US3312006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:23

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute myocardial infarction, LLT: Acute myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Apr 2021 19:17:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Apr 2021 19:17:00
Data point term sent to Coder	System	02 Apr 2021 19:15:51
User entered 'Acute myocardial infarction'	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

US3312006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:23

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'No (N)'	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

US3312006
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:00:23
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'No (N)'	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

FDA-CBER-2022-1614-0853029

US3312006
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:00:23
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'No (N)'	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

US3312006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:23

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered '09 Mar 2021'	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

US3312006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered empty.	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered empty.	System	02 Apr 2021 19:15:50

FDA-CBER-2022-1614-0853033

US3312006
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:00:23
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'No (N)'	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered '09 Mar 2021'	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

US3312006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered empty.	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

US3312006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:23

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered empty.	System	02 Apr 2021 19:15:50

US3312006
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:00:23
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'Grade 4 (Grade 4)'	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

US3312006
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:00:23
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'Yes (Y)'	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

US3312006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:23

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User closed query 'Per CDM: Please complete Study discontinuation form accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 05:09:46
Query 'Per CDM: Please complete Study discontinuation form accordingly.' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	12 Apr 2021 17:54:20
User opened query 'Per CDM: Please complete Study discontinuation form accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Apr 2021 08:00:51
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered '1'	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

US3312006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:23

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered '0'	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered '0'	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

US3312006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:23

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered empty.	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered empty.	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

FDA-CBER-2022-1614-0853044

US3312006
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:00:23
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered empty.	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

US3312006
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:00:23

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered empty.	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

US3312006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:23

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered '0'	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

US3312006
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:00:23
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered '0'	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

US3312006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:23

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered '0'	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

US3312006
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:00:23
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'Not Related (NOT RELATED)'	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

US3312006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:23

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'Not Related (NOT RELATED)'	Heather Barker (b) (4)	02 Apr 2021 19:15:50

US3312006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:23

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'Not Applicable (NOT APPLICABLE)'	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

US3312006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:23

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered '1'	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

US3312006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:23

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered '0'	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

US3312006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:23

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered '0'	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

US3312006
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:00:23
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'Fatal (FATAL)'	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

US3312006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered empty.	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Apr 2021 19:42:09
User closed query 'PV Query: Please confirm if the subject was taking any concomitant medications for bradycardia/hypertension (within 30 days of the event).' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 17:20:40
User closed query 'PV Query: Please consider adding hypertension to the medical history.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 17:20:37
Signature has been broken.	Karol Moore (b) (4) (b) (4)	13 Apr 2021 20:31:20
User entered 'SITE ATTEMPTED TO CONTACT SUBJECT FOR ROUTINE FOLLOW-UP, NOTIFIED BY SPOUSE OF SUBJECT'S DEMISE. SPOUSE REPORTED THAT ON 09MAR2021 SHE AWOKE TO FIND SUBJECT HAD DIED DURING THE NIGHT, PRONOUNCED BY EMS AT 0726 09MAR2021. AUTOPSY PERFORMED ON 10MAR2021 REVEALED CAUSE OF DEATH TO BE HYPERTENSIVE AND ATHEROSCLEROTIC CARDIOVASCULAR DISEASE. HX OF WHITE COAT HYPERTENSION HTN AND BRADYCARDIA KNOWN TO OUR SITE, REPORTEDLY FOLLOWED BY PCP.' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	13 Apr 2021 20:31:20
Query 'PV Query: Please confirm if the subject was taking any concomitant medications for bradycardia/hypertension (within 30 days of the event).' answered with 'CONFIRMED NO MEDICATIONS FOR EITHER INDICATION' (Site from Safety).	Karol Moore (b) (4) (b) (4)	13 Apr 2021 20:26:36
Query 'PV Query: Please consider adding hypertension to the medical history.' answered with 'PER PI, WHITE COAT HYPERTENSION ADDED TO MEDICAL HISTORY' (Site from Safety).	Karol Moore (b) (4) (b) (4)	13 Apr 2021 20:25:59
User opened query 'PV Query: Please confirm if the subject was taking any concomitant medications for bradycardia/hypertension (within 30 days of the event).' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 19:29:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:23

Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please consider adding hypertension to the medical history.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 19:28:49
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'Site attempted to contact subject for routine follow-up, notified by spouse of subject's demise. Spouse reported that on 09Mar2021 she awoke to find subject had died during the night, pronounced by EMS at 0726 09Mar2021. Autopsy performed on 10Mar2021 revealed cause of death to be hypertensive and atherosclerotic cardiovascular disease. Hx of HTN and bradycardia known to our site, reportedly followed by PCP.'	Heather Barker (b) (4) (b) (4)	02 Apr 2021 19:15:50

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Folder: Adverse Events

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Generated On: 09 Jun 2021 17:00:23

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered '1'	System	02 Apr 2021 19:15:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:23

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered '0'	System	02 Apr 2021 19:15:50

US3312006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:23

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:07:39

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:23

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 14:10:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 14:10:25
Data point term sent to Coder	System	12 Aug 2020 14:09:08
User entered 'multivitamin'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:08:42

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:23

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:08:42

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:23

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'health maintenance'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:08:42

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:23

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered '1'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:08:42

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:23

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'tablet (TABLET)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:08:42

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered empty.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:08:42

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:23

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'once daily (QD)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:08:42

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered empty.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:08:42

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:23

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'Oral (ORAL)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:08:42

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered empty.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:08:42

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:23

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 14:21:59
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 14:08:42
User entered 'un UNK 1988'	Kelly Moen (b) (4)	12 Aug 2020 14:08:42

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:23

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered '0'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:08:42

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:23

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:08:42

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered empty.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:08:42

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:23

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:08:42

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:23

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered '1'	System	12 Aug 2020 14:08:42

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:23

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered '1'	System	12 Aug 2020 14:08:42

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered '804 (804)'	System	12 Aug 2020 14:08:42

FDA-CBER-2022-1614-0853081

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:23

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 14:11:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 14:11:28
Data point term sent to Coder	System	12 Aug 2020 14:10:11
User entered 'Fish oil'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:09:41

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:23

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:09:41

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:23

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
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.' canceled (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 05:50:42
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)	23 Sep 2020 05:50:38
User entered 'health maintenance'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:09:41

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:23

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User closed query ' PER DM CLR Requery -Response noted,however as per response,exact dose is unknown,so kindly consider to update 'UNK' in the field 'dose per administration'.Thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 11:59:40
Query ' PER DM CLR Requery -Response noted,however as per response,exact dose is unknown,so kindly consider to update 'UNK' in the field 'dose per administration'.Thank you. ' answered with 'updated' (Site from DM).	Karol Moore (b) (4) (b) (4)	03 Nov 2020 16:59:06
User entered '1200' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	03 Nov 2020 16:59:01
User opened query ' PER DM CLR Requery -Response noted,however as per response,exact dose is unknown,so kindly consider to update 'UNK' in the field 'dose per administration'.Thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:31:54
Query 'RE DM CLR Requery -Response noted,however as per response,exact dose is unknown,so kindly consider to update 'UNK' in the field 'dose per administration'.Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:31:43
User opened query 'RE DM CLR Requery -Response noted,however as per response,exact dose is unknown,so kindly consider to update 'UNK' in the field 'dose per administration'.Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:29:42
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)	21 Oct 2020 09:29:42
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 'CORRECT AS ENTERED. EXACT DOSE UNKNOWN' (Site from DM).	Karol Moore (b) (4) (b) (4)	20 Oct 2020 22:21:47

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:23

Dose per administration

Audit	User	Time (GMT)
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)	23 Sep 2020 05:50:50
User entered '1'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:09:41

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:23

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'mg (mg)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	03 Nov 2020 16:59:01
User entered 'tablet (TABLET)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:09:41

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered empty.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:09:41

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:23

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'once daily (QD)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:09:41

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered empty.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:09:41

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:23

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'Oral (ORAL)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:09:41

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered empty.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:09:41

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:23

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 14:22:05
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 14:09:41
User entered 'un UNK 2015'	Kelly Moen (b) (4)	12 Aug 2020 14:09:41

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:23

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered '0'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:09:41

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:23

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:09:41

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered empty.	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:09:41

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:23

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	12 Aug 2020 14:09:41

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered '1'	System	12 Aug 2020 14:09:41

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:23

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered '1'	System	12 Aug 2020 14:09:41

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:23

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered '804 (804)'	System	12 Aug 2020 14:09:41

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:23

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
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)	03 Nov 2020 17:00:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 17:00:25
Data point term sent to Coder	System	03 Nov 2020 17:00:16
User entered 'seasonal influenza vaccine'	Karol Moore (b) (4) (b) (4)	03 Nov 2020 17:00:05

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:23

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	03 Nov 2020 17:00:05

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:23

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'seasonal influenza vaccine'	Karol Moore (b) (4)	03 Nov 2020 17:00:05

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:23

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered '0.5' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 14:33:09
User entered '1'	Karol Moore (b) (4)	03 Nov 2020 17:00:05

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:23

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 14:33:09
User entered 'Other (OTHER)'	Karol Moore (b) (4)	03 Nov 2020 17:00:05

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 14:33:09
User entered 'injection'	Karol Moore (b) (4) (b) (4)	03 Nov 2020 17:00:05

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:23

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'once (ONCE)'	Karol Moore (b) (4)	03 Nov 2020 17:00:05

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered empty.	Karol Moore (b) (4) (b) (4)	03 Nov 2020 17:00:05

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:23

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'Intramuscular (INTRAMUSCULAR)'	Karol Moore (b) (4) (b) (4)	03 Nov 2020 17:00:05

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered empty.	Karol Moore (b) (4) (b) (4)	03 Nov 2020 17:00:05

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:23

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered '22 Oct 2020'	Karol Moore (b) (4)	03 Nov 2020 17:00:05

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:23

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered '0'	Karol Moore (b) (4)	03 Nov 2020 17:00:05

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:23

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'No (N)'	Karol Moore (b) (4)	03 Nov 2020 17:00:05

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered '22 Oct 2020'	(b) (4) Karol Moore (b) (4)	03 Nov 2020 17:00:05
	(b) (4)	

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:23

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	03 Nov 2020 17:00:05

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:23

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered empty.	System	03 Nov 2020 17:00:05

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:23

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered empty.	System	03 Nov 2020 17:00:05

US3312006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:23

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered empty.	System	03 Nov 2020 17:00:05

US3312006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:00:23

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
User entered 'No (N)'	(b) (4), (b) (6)	18 Feb 2021 15:12:59

US3312006

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:00:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:44:36
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Apr 2021 19:42:09
User entered '09 Mar 2021'	Karol Moore (b) (4) (b) (4)	12 Apr 2021 18:08:10

US3312006

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:00:23

Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:44:36
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Apr 2021 19:42:09
User closed query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	System	12 Apr 2021 18:08:51
User entered 'Death (DEATH)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	12 Apr 2021 18:08:51
User opened query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	System	12 Apr 2021 18:08:10
User entered 'SAE (specify) (SAE)'	Karol Moore (b) (4) (b) (4)	12 Apr 2021 18:08:10

US3312006

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:00:23

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)	27 Apr 2021 11:44:36
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Apr 2021 19:42:09
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4) (b) (4)	12 Apr 2021 18:08:51
User entered 'ACUTE MYOCARDIA INFARCTION'	Karol Moore (b) (4) (b) (4)	12 Apr 2021 18:08:10

FDA-CBER-2022-1614-0853122

US3312006
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:00:23
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:44:36
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:42:09
User entered 'Adverse event (ADVERSE EVENT)'	Karol Moore (b) (4)	12 Apr 2021 18:08:10

Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:00:23
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:44:36
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Apr 2021 19:42:09
User entered empty.	Karol Moore (b) (4) (b) (4)	12 Apr 2021 18:08:10

US3312006

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:00:23

Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:44:36
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Apr 2021 19:42:09
User entered '09 Mar 2021'	Karol Moore (b) (4) (b) (4)	12 Apr 2021 18:08:10

US3312006
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:00:23
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:44:36
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Apr 2021 19:42:09
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	12 Apr 2021 18:08:10

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'USA-US300-2021-MRNA-1273-P301000022'	System	05 Apr 2021 13:18:46

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'Yes (Y)'	System	05 Apr 2021 13:18:46

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'Yes (Y)'	System	05 Apr 2021 13:18:46

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'No (N)'	System	05 Apr 2021 13:18:46

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'No (N)'	System	05 Apr 2021 13:18:46

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'No (N)'	System	05 Apr 2021 13:18:46

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'No (N)'	System	05 Apr 2021 13:18:46

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'No (N)'	System	05 Apr 2021 13:18:46

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'Carlos'	System	05 Apr 2021 13:18:46

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'Fierro'	System	05 Apr 2021 13:18:46

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered '16300 College Blvd'	System	05 Apr 2021 13:18:46

FDA-CBER-2022-1614-0853137

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'Shawnee'	System	05 Apr 2021 13:18:46

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'KS'	System	05 Apr 2021 13:18:46

FDA-CBER-2022-1614-0853139

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered '66219'	System	05 Apr 2021 13:18:46

FDA-CBER-2022-1614-0853140

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 17:11:05
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'US'	System	05 Apr 2021 13:20:32

FDA-CBER-2022-1614-0853141

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered '2'	System	14 Apr 2021 17:11:34
User entered '1'	System	05 Apr 2021 13:20:32

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'USA-US300-2021-MRNA-1273-P301000022'	System	05 Apr 2021 13:18:46

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'Yes (Y)'	System	05 Apr 2021 13:18:46

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'Yes (Y)'	System	05 Apr 2021 13:18:46

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'No (N)'	System	05 Apr 2021 13:18:46

FDA-CBER-2022-1614-0853146

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'No (N)'	System	05 Apr 2021 13:18:46

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'No (N)'	System	05 Apr 2021 13:18:46

FDA-CBER-2022-1614-0853148

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'No (N)'	System	05 Apr 2021 13:18:46

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'No (N)'	System	05 Apr 2021 13:18:46

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'Carlos'	System	05 Apr 2021 13:18:46

FDA-CBER-2022-1614-0853151

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'Fierro'	System	05 Apr 2021 13:18:46

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered '16300 College Blvd'	System	05 Apr 2021 13:18:46

FDA-CBER-2022-1614-0853153

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'Shawnee'	System	05 Apr 2021 13:18:46

FDA-CBER-2022-1614-0853154

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'KS'	System	05 Apr 2021 13:18:46

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered '66219'	System	05 Apr 2021 13:18:46

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 17:11:05
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'US'	System	05 Apr 2021 13:20:32

US3312006

Folder: SAE USA-US300-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:23

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered '2'	System	14 Apr 2021 17:11:34
User entered '1'	System	05 Apr 2021 13:20:32

US3312006

Folder: SAE USA-US300-2021-MRNA-1273-P301000022

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:00:23

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered '05/Apr/2021 09:20'	System	05 Apr 2021 13:20:32

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 17:11:05
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered '1'	(b) (4), (b) (6)	05 Apr 2021 13:20:32

US3312006

Folder: SAE USA-US300-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:23

SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'USA-US300-2021-MRNA-1273-P301000022'	System	05 Apr 2021 13:18:46

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'Yes (Y)'	System	05 Apr 2021 13:18:46

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'Yes (Y)'	System	05 Apr 2021 13:18:46

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'No (N)'	System	05 Apr 2021 13:18:46

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'No (N)'	System	05 Apr 2021 13:18:46

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'No (N)'	System	05 Apr 2021 13:18:46

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'No (N)'	System	05 Apr 2021 13:18:46

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'No (N)'	System	05 Apr 2021 13:18:46

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'Carlos'	System	05 Apr 2021 13:18:46

FDA-CBER-2022-1614-0853169

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'Fierro'	System	05 Apr 2021 13:18:46

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered '16300 College Blvd'	System	05 Apr 2021 13:18:46

FDA-CBER-2022-1614-0853171

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'Shawnee'	System	05 Apr 2021 13:18:46

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered 'KS'	System	05 Apr 2021 13:18:46

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:20:26
User entered '66219'	System	05 Apr 2021 13:18:46

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 17:11:05
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 17:19:30
User entered 'US'	System	05 Apr 2021 13:20:32

US3312006
Folder: SAE USA-US300-2021-MRNA-1273-P301000022
Form: Safety Report Form
Generated On: 09 Jun 2021 17:00:23

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User entered '2'	System	14 Apr 2021 17:11:34
User entered '1'	System	05 Apr 2021 13:20:32

US3312006

Folder: SAE USA-US300-2021-MRNA-1273-P301000022

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:00:23

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Apr 2021 19:42:09
User entered '14/Apr/2021 13:11'	System	14 Apr 2021 17:11:34

US3312006

Folder: SAE USA-US300-2021-MRNA-1273-P301000022

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:00:23

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:10:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:42:09
User entered '1'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:11:34