

US3312573 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:12:27

All time stamps listed in this document are displayed in GMT

US3312573

Form: Participant Creation

Data signed: (b) (4) 12 Mar 2021 15:36:09

Generated On: 11 Aug 2021 22:12:27

[Participant ID](#)

US3312573

[mRNA-1273-P301 Completion Guidelines](#)

US3312573

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	09 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3312573

Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

Date of Birth (MMM yyyy)	(b) (6) 1986
Age	34
Age Units	YEARS
Age (Derived)	34
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

US3312573

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

Date of Informed Consent (dd MMM yyyy)	9 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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

US3312573

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3312573

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

Were any significant conditions reported?

Yes ☐

No ☒

US3312573

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	09 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	12:33 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 12:33
Height (<i>xxx.x</i>)	67 in
Weight (<i>xxx.x</i>)	194 lb
BMI (<i>xxx.x</i>)	30.44823 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312573

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 SEP 2020

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

US3312573

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

Date of assessment (dd MMM yyyy) 09 SEP 2020

Is the participant of childbearing potential? Yes ☒
No ☐

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☐
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (dd MMM yyyy) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (dd MMM yyyy) _____
Date of last menstruation unknown False

US3312573

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 09 SEP 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3312573

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

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

US3312573

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

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

US3312573

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	9 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3312573

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

What was the date of randomization? (dd MMM yyyy) 09 SEP 2020

What was the participant's randomization number? 112782

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☒
 >=18 and <65 years and at risk ☐
 >=65 years ☐

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

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m²) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

Height	ND - Not Done
Weight	ND - Not Done

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

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)	09 SEP 2020
Time of assessment (00:00-23:59)	12:33 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 12:33
Temperature (xxx.x)	98.0 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

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)	09 SEP 2020
Time of assessment (00:00-23:59)	14:27 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 14:27
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3312573

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

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.

US3312573

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☐

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3312573

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

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) 09 SEP 2020

What was the treatment time? (00:00-23:59) 13:56 (24 HR)

Treatment Date and Time (derived) 09 SEP 2020 13:56

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

US3312573

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

09 SEP 2020

Collection time (00:00-23:59)

12:56 (24 HR)

Collection date and time (derived)

09 SEP 2020 12:56

US3312573

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

Collection date (dd MMM yyyy)			09 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:41	09 SEP 2020 12:41
Nasopharyngeal Swab 2	No		

US3312573

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

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

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 14:26

PC Open Date & Time

09 SEP 2020 14:16

PC Close Date & Time

09 SEP 2020 16:46

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

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 98.3 °F

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

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

PC Time Stamp	09 SEP 2020 18:14
PC Open Date & Time	09 SEP 2020 17:41
PC Close Date & Time	10 SEP 2020 11:59

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:12:27

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 SEP 2020 00:00

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:12:27

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 00:01

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:12:27

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 22:13

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 21:11

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

DAY 6

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

14 SEP 2020 21:18

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:12:27

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

16 SEP 2020 00:02

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

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

09 SEP 2020 14:27

PC Open Date & Time

09 SEP 2020 14:16

PC Close Date & Time

09 SEP 2020 16:46

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

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

09 SEP 2020 18:15

PC Open Date & Time

09 SEP 2020 17:41

PC Close Date & Time

10 SEP 2020 11:59

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 00:00

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 00:02

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 22:13

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 21:11

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 21:19

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 00:02

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

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 ☐

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 14:27
PC Open Date & Time	09 SEP 2020 14:16
PC Close Date & Time	09 SEP 2020 16:46

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

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 ☐

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 18:15
PC Open Date & Time	09 SEP 2020 17:41
PC Close Date & Time	10 SEP 2020 11:59

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:27

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

44 of 770

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:27

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

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:27

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 ☒

PRODUCTION RELEASE (v12.003

46 of 770

EAB) (1725)

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:27

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

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:27

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

48 of 770

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:27

Yes ☐	
PC Time stamp	12 SEP 2020 22:13
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

50 of 770

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:27

Yes ☐	
PC Time stamp	13 SEP 2020 21:11
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:27

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 ☒

PRODUCTION RELEASE (v12.003

52 of 770

EAB) (1725)

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:27

Yes ☐	
PC Time stamp	14 SEP 2020 21:19
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:27

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

54 of 770

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:27

Yes ☐	
PC Time stamp	16 SEP 2020 00:02
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3312573

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312573

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312573

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312573

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312573

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312573

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312573

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 20:58:02

Generated On: 11 Aug 2021 22:12:27

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	7 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 20:58:02

Generated On: 11 Aug 2021 22:12:27

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	07 OCT 2020
Time of assessment (00:00-23:59)	09:26 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 09:26
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 20:58:02

Generated On: 11 Aug 2021 22:12:27

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	07 OCT 2020
Time of assessment (00:00-23:59)	11:31 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 11:31
Temperature (xxx.x)	98.0 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3312573

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 20:58:02

Generated On: 11 Aug 2021 22:12:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 OCT 2020

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

US3312573

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 20:58:02

Generated On: 11 Aug 2021 22:12:27

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 07 OCT 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3312573

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 20:58:02

Generated On: 11 Aug 2021 22:12:27

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) 07 OCT 2020

What was the treatment time? (00:00-23:59) 11:00 (24 HR)

Treatment Date and Time (derived) 07 OCT 2020 11:00

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3312573

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 20:58:02

Generated On: 11 Aug 2021 22:12:27

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

07 OCT 2020

Collection time (00:00-23:59)

10:11 (24 HR)

Collection date and time (derived)

07 OCT 2020 10:11

US3312573

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 20:58:02

Generated On: 11 Aug 2021 22:12:27

Collection date (dd MMM yyyy)			07 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:57	07 OCT 2020 09:57
Nasopharyngeal Swab 2	No		

US3312573

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:58:02

Generated On: 11 Aug 2021 22:12:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312573

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

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

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 11:33

PC Open Date & Time

07 OCT 2020 11:20

PC Close Date & Time

07 OCT 2020 13:50

US3312573

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

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 98.3 °F

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

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

PC Time Stamp	08 OCT 2020 09:52
PC Open Date & Time	07 OCT 2020 14:45
PC Close Date & Time	08 OCT 2020 11:59

US3312573

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 11:33

PC Open Date & Time

07 OCT 2020 11:20

PC Close Date & Time

07 OCT 2020 13:50

US3312573

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

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

08 OCT 2020 09:52

PC Open Date & Time

07 OCT 2020 14:45

PC Close Date & Time

08 OCT 2020 11:59

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

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 ☐

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 11:34
PC Open Date & Time	07 OCT 2020 11:20
PC Close Date & Time	07 OCT 2020 13:50

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

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 ☐

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 09:52
PC Open Date & Time	07 OCT 2020 14:45
PC Close Date & Time	08 OCT 2020 11:59

US3312573

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 19:10:08

Generated On: 11 Aug 2021 22:12:27

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 OCT 2020

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

Comments MESSAGE LEFT ON 10/14, 10/15
AND 10/16. SUBJECT DID NOT
RETURN CALL.
If Contact Not Made, please provide Comments

US3312573

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312573

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 19:10:08

Generated On: 11 Aug 2021 22:12:27

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 OCT 2020

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

Comments MESSAGE LEFT ON 10/21, 10/22,
AND 10/23. SUBJECT DID NOT
RETURN CALL.
If Contact Not Made, please provide Comments

US3312573

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312573

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 19:10:08

Generated On: 11 Aug 2021 22:12:27

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 OCT 2020

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

Comments MESSAGE LEFT ON 10/28, 10/29,
AND 10/30. SUBJECT DID NOT
RETURN CALL.

If Contact Not Made, please provide Comments

US3312573

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:58:01

Generated On: 11 Aug 2021 22:12:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312573

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 20:58:02

Generated On: 11 Aug 2021 22:12:27

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT3

US3312573

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 20:58:02

Generated On: 11 Aug 2021 22:12:27

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3312573

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 20:58:02

Generated On: 11 Aug 2021 22:12:27

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.

US3312573

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 20:58:02

Generated On: 11 Aug 2021 22:12:27

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3312573

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:58:02

Generated On: 11 Aug 2021 22:12:27

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3312573

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:12:27

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

US3312573

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:12:27

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 ☐

US3312573

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:12:27

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3312573

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

Form: Visit Date

Generated On: 11 Aug 2021 22:12:27

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3312573

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

Form: Unblinding

Generated On: 11 Aug 2021 22:12:27

Date of updated informed consent (<i>dd MMM yyyy</i>)		
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study		
Was the participant unblinded?	Yes	☐
	No	☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5	☐
	Amendment 6 or later	☐
Date of unblinding (<i>dd MMM yyyy</i>)		
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		

US3312573

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:27

Was the sample collected?	Yes ☐
	No ☐

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3312573

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:12:27

Was the sample collected?	Yes ☐
	No ☐
Collection date (<i>dd MMM yyyy</i>)	
Collection time (<i>00:00 - 23:59</i>)	
Collection Date and Time (derived)	

US3312573

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 07 Apr 2021 19:10:08

Generated On: 11 Aug 2021 22:12:27

Did the participant experience any adverse events?

Yes ☐

No ☒

If Yes, enter details on the Adverse Events form.

US3312573

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Mar 2021 15:36:10

Generated On: 11 Aug 2021 22:12:27

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

Yes ☒

No ☐

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

US3312573

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Mar 2021 15:36:09

Generated On: 11 Aug 2021 22:12:27

Name of Medication NEXPLANON

Prophylaxis Yes ☒
No ☐

Indication BIRTH CONTROL

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify IMPANT

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 ONCE EVERY 3 YEARS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

103 of 770

US3312573

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Mar 2021 15:36:09

Generated On: 11 Aug 2021 22:12:27

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	SUBDERMAL	
Start date (dd MMM yyyy)	UN JAN 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3312573

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 07 Apr 2021 19:10:08

Generated On: 11 Aug 2021 22:12:27

[Were any concomitant procedures performed?](#)

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3312573

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 12 Mar 2021 15:36:10

Generated On: 11 Aug 2021 22:12:27

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

US3312573

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 07 Apr 2021 19:10:08

Generated On: 11 Aug 2021 22:12:27

Date of study discontinuation/completion (dd MMM yyyy) 31 OCT 2020

Reason for discontinuation

AE (specify)	☐
SAE (specify)	☐
Complete	☐
Death	☐
Lost To Follow-up	☒
Physician decision (specify)	☐
Pregnancy	☐
Protocol deviation (specify)	☐
Study Terminated By Sponsor	☐
Withdrawal of consent by participant (specify)	☐
Other	☐

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

If reason for discontinuation is Death, main cause of death

Adverse event	☐
Unknown	☐
Other	☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes	☐
No	☐
Unknown	☐

Audit

US3312573 (Prod: Johnson County Clin-Trials)

US3312573

Form: Participant Creation

Generated On: 11 Aug 2021 22:12:27

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User entered 'US3312573'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 17:20:56

US3312573

Form: Participant Creation

Generated On: 11 Aug 2021 22:12:27

[mRNA-1273-P301 Completion Guidelines](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04

US3312573

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:12:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User closed query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed. (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 22:06:00
Query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed.	Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:05:25
' answered with 'UPDATED' (Site from DM).		
User opened query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed. (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 17:30:36
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	09 Sep 2020 19:00:06

US3312573

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:12:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '09 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 17:20:57

US3312573

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:12:27

[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 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	09 Sep 2020 19:00:06

US3312573

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:12:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered 'SCRN'	System	09 Sep 2020 19:00:06

US3312573

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:27

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered (b) (6) 1986'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 17:20:58

US3312573

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:27

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '34'	Christa Estrada (b) (4)	09 Sep 2020 19:00:19

US3312573

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:27

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered 'YEARS'	System	09 Sep 2020 19:00:19

US3312573

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:27

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered '34'	System	09 Sep 2020 19:00:33

US3312573

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:27

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Female (F)'	Christa Estrada (b) (4)	09 Sep 2020 19:00:19

US3312573

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:27

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Christa Estrada (b) (4)	09 Sep 2020 19:00:19

US3312573

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:27

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '1'	Christa Estrada (b) (4)	09 Sep 2020 19:00:19

US3312573

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:27

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '0'	Christa Estrada (b) (4)	09 Sep 2020 19:00:19

US3312573

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:27

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '0'	Christa Estrada (b) (4)	09 Sep 2020 19:00:19

US3312573

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:27

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '0'	Christa Estrada (b) (4)	09 Sep 2020 19:00:19

US3312573

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:27

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '0'	Christa Estrada (b) (4)	09 Sep 2020 19:00:19

US3312573

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:27

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '0'	Christa Estrada (b) (4)	09 Sep 2020 19:00:19

US3312573

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:27

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Christa Estrada (b) (4)	09 Sep 2020 19:00:19

US3312573

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:27

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '0'	Christa Estrada (b) (4)	09 Sep 2020 19:00:19

US3312573

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:27

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '0'	Christa Estrada (b) (4)	09 Sep 2020 19:00:19

US3312573

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:27

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '9 Sep 2020'	Christa Estrada (b) (4)	09 Sep 2020 19:00:33

US3312573

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:27

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered 'Sep 2020'	System	09 Sep 2020 19:00:33

US3312573

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:27

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered '2020'	System	09 Sep 2020 19:00:33

US3312573

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:27

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Amendment 3 (3)'	Christa Estrada (b) (4)	09 Sep 2020 19:00:33

US3312573

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:27

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	09 Sep 2020 19:00:33

US3312573

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:27

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	Christa Estrada (b) (4)	09 Sep 2020 19:00:33

US3312573

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:27

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Christa Estrada (b) (4)	09 Sep 2020 19:00:33

US3312573

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:27

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	09 Sep 2020 19:00:33

US3312573

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:27

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 17:20:57

US3312573

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:27

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered '1'	System	09 Sep 2020 19:00:39

US3312573

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:12:27

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	Christa Estrada (b) (4)	09 Sep 2020 19:00:39

US3312573

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:12:27

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	(b) (4)	29 Sep 2020 17:05:33
	Karol Moore (b) (4)	
	(b) (4)	

US3312573

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:09:50

US3312573

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '09 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:09:50

US3312573

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '12:33'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:09:50

US3312573

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered '09 Sep 2020 12:33'	System	29 Sep 2020 17:09:50

US3312573

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '67' in	(b) (4)	29 Sep 2020 17:09:50
DataPoint set to visible.	Karol Moore (b) (4)	09 Sep 2020 19:00:39
	(b) (4)	
	System	

US3312573

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '194' lb	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:09:50
DataPoint set to visible.	(b) (4) System	09 Sep 2020 19:00:39

US3312573

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered '30.44823'	System	29 Sep 2020 17:09:50
DataPoint set to visible.	System	09 Sep 2020 19:00:39

US3312573

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered 'kg/m2'	System	29 Sep 2020 17:09:50
DataPoint set to visible.	System	09 Sep 2020 19:00:39

US3312573

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:09:50

US3312573

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:09:50

US3312573

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:09:50

US3312573

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:09:50

US3312573

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered 'bpm'	System	29 Sep 2020 17:09:50

US3312573

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:09:50

US3312573

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered 'breaths/min'	System	29 Sep 2020 17:09:50

US3312573

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:09:50

US3312573

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered 'mmHg'	System	29 Sep 2020 17:09:50

US3312573

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:09:50

US3312573

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered 'mmHg'	System	29 Sep 2020 17:09:50

US3312573

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55

US3312573

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55

US3312573

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:10:02

US3312573

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:27

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '09 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:10:02

US3312573

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:12:27

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '09 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:10:15

US3312573

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:12:27

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:10:15

US3312573

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:12:27

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:10:15

US3312573

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:12:27

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:10:15

US3312573

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:10:15

US3312573

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:12:27

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:10:15

US3312573

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4)	29 Sep 2020 17:10:15
	Karol Moore (b) (4)	
	(b) (4)	

US3312573

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:12:27

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:10:15

US3312573

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:27

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:10:27

US3312573

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:27

[Date of test \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '09 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:10:27

US3312573

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:27

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Urine (URINE)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:10:27

US3312573

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:27

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Negative (NEGATIVE)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:10:27

US3312573

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:27

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:10:27

US3312573

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:27

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:10:27

US3312573

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:27

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4)	29 Sep 2020 17:10:27
	Karol Moore (b) (4)	
	(b) (4)	

US3312573

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered empty.	System	29 Sep 2020 17:10:27

US3312573

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:27

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 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:10:57

US3312573

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:27

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 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:10:57

US3312573

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:27

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 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:10:57

US3312573

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:27

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 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:10:57

US3312573

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:27

[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 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	(b) (4)	29 Sep 2020 17:10:57
	Karol Moore (b) (4)	
	(b) (4)	

US3312573

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:27

[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 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:10:57

US3312573

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:27

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 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	Karol Moore (b) (4)	29 Sep 2020 17:10:57

US3312573

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:27

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 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	Karol Moore (b) (4)	29 Sep 2020 17:10:57

US3312573

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:27

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 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:10:57

US3312573

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:27

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 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:10:57
	(b) (4)	

US3312573

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:27

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 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:10:57

US3312573

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:27

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	(b) (4)	29 Sep 2020 17:10:57
	Karol Moore (b) (4)	
	(b) (4)	

US3312573

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4)	29 Sep 2020 17:10:57
	Karol Moore (b) (4)	
	(b) (4)	

US3312573

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:27

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:10:57

US3312573

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:27

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '0'	(b) (4)	29 Sep 2020 17:10:57
	Karol Moore (b) (4)	
	(b) (4)	

US3312573

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:27

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 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:10:57

US3312573

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:27

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 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:10:57

US3312573

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:27

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 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:10:57

US3312573

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:10:57

US3312573

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:27

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '1'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:10:57

US3312573

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'RESIDES IN COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:10:57

US3312573

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:12:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	Christa Estrada (b) (4)	09 Sep 2020 19:00:49

US3312573

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:12:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '9 Sep 2020'	Christa Estrada (b) (4)	09 Sep 2020 19:00:49

US3312573

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:12:27

[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 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	09 Sep 2020 19:00:49

US3312573

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:12:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered 'VISIT1'	System	09 Sep 2020 19:00:49

US3312573

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '09 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 18:29:52

US3312573

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:27

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '112782'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 18:29:52

US3312573

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:27

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 18:29:52

US3312573

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	Christa Estrada (b) (4)	09 Sep 2020 19:01:00

US3312573

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	Christa Estrada (b) (4)	09 Sep 2020 19:01:00

US3312573

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	Christa Estrada (b) (4)	09 Sep 2020 19:01:00

US3312573

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:27

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	Christa Estrada (b) (4)	09 Sep 2020 19:01:00

US3312573

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:27

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	Christa Estrada (b) (4)	09 Sep 2020 19:01:00

US3312573

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:27

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:11:06
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 05:50:50
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:50:49

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:27

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:27

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '09 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '12:33'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User entered '09 Sep 2020 12:33'	System	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '98.0' F	(b) (4)	29 Sep 2020 17:11:53
	Karol Moore (b) (4)	
	(b) (4)	

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '80'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User entered 'bpm'	System	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '12'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User entered 'breaths/min'	System	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '135'	(b) (4)	29 Sep 2020 17:11:53
	Karol Moore (b) (4)	
	(b) (4)	

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User entered 'mmHg'	System	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '90'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User entered 'mmHg'	System	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:27

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '09 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '14:27'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User entered '09 Sep 2020 14:27'	System	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '97.9' F	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4)	29 Sep 2020 17:11:53
	Karol Moore (b) (4)	
	(b) (4)	

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '58'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User entered 'bpm'	System	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '16'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User entered 'breaths/min'	System	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '124'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User entered 'mmHg'	System	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '83'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:31:06
User entered 'mmHg'	System	29 Sep 2020 17:11:53

US3312573

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:11:57

US3312573

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:27

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:11:57

US3312573

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:27

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	(b) (4)	29 Sep 2020 17:12:01
	Karol Moore (b) (4)	
	(b) (4)	

US3312573

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:27

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4)	29 Sep 2020 17:12:01
	Karol Moore (b) (4)	
	(b) (4)	

US3312573

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:27

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:12:01

US3312573

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:27

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:12:01

US3312573

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:27

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4)	29 Sep 2020 17:12:01
	Karol Moore (b) (4)	
	(b) (4)	

US3312573

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:27

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:12:01

US3312573

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:27

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:12:01

US3312573

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered empty.	System	29 Sep 2020 17:12:01

US3312573

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	Christa Estrada (b) (4)	09 Sep 2020 19:01:24

US3312573

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:27

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	Christa Estrada (b) (4)	09 Sep 2020 19:01:24

US3312573

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	Christa Estrada (b) (4)	09 Sep 2020 19:01:24

US3312573

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 19:01:24

US3312573

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User closed query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:13:48
' (Site from DM).		
Query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	Heather Barker (b) (4)	21 Oct 2020 18:54:50
' answered with 'updated' (Site from DM).	(b) (4)	
User entered '09 Sep 2020' reason for change: Data Entry Error	Heather Barker (b) (4)	21 Oct 2020 18:54:42
User opened query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	(b) (4), (b) (6)	14 Oct 2020 15:42:36
' (Site from DM).		
Un-reviewed for Data Management.	(b) (4), (b) (6)	14 Oct 2020 15:42:32
Reviewed for Data Management.	(b) (4), (b) (6)	14 Oct 2020 15:42:29
User entered '9 Sep 2020'	Christa Estrada (b) (4)	09 Sep 2020 19:01:24
	(b) (4)	

US3312573

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:27

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '13:56'	Christa Estrada (b) (4)	09 Sep 2020 19:01:24

US3312573

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:27

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered '09 Sep 2020 13:56'	System	21 Oct 2020 18:54:42
User entered '9 Sep 2020 13:56'	System	09 Sep 2020 19:01:24

US3312573

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:27

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4)	09 Sep 2020 19:01:24

US3312573

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:27

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered 'ONCE'	System	09 Sep 2020 19:01:24

US3312573

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:27

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 19:01:24

US3312573

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:12:13

US3312573

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '09 Sep 2020'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:12:13

US3312573

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '12:56'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:12:13

US3312573

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered '09 Sep 2020 12:56'	System	29 Sep 2020 17:12:13

US3312573

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:12:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '09 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:12:24

US3312573

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:12:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:12:24

US3312573

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:12:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:12:24

US3312573

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:12:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '12:41'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:12:24

US3312573

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:12:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered '09 Sep 2020 12:41'	System	29 Sep 2020 17:12:24

US3312573

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:12:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:12:24

US3312573

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:12:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:12:24

US3312573

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:12:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:12:24

US3312573

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:12:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered empty.	System	29 Sep 2020 17:12:24

US3312573

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:12:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4)	29 Sep 2020 17:12:29
	Karol Moore (b) (4)	
	(b) (4)	

US3312573

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:12:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered '1'	System	29 Sep 2020 17:12:29

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T14:26:14', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'ea108cc1-091d-4b6a-942c-4ada080a0902'	System	09 Sep 2020 19:26:40
User entered 'Yes (Y)'	System	09 Sep 2020 19:26:40

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T14:26:21', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'ea108cc1-091d-4b6a-942c-4ada080a0902'	System	09 Sep 2020 19:26:40
User entered '97.9'	System	09 Sep 2020 19:26:40

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T14:26:31', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'ea108cc1-091d-4b6a-942c-4ada080a0902'	System	09 Sep 2020 19:26:40
User entered 'No (N)'	System	09 Sep 2020 19:26:40

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T14:26:36', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'ea108cc1-091d-4b6a-942c-4ada080a0902'	System	09 Sep 2020 19:26:40
User entered '09 Sep 2020 14:26'	System	09 Sep 2020 19:26:40

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '09 Sep 2020 14:16'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '09 Sep 2020 16:46'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T18:14:32', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'c520ef2d-529d-4515-8f6a-f6d140544241'	System	09 Sep 2020 23:14:45
User entered 'Yes (Y)'	System	09 Sep 2020 23:14:45

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T18:14:36', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'c520ef2d-529d-4515-8f6a-f6d140544241'	System	09 Sep 2020 23:14:45
User entered '98.3'	System	09 Sep 2020 23:14:45

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T18:14:40', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'c520ef2d-529d-4515-8f6a-f6d140544241'	System	09 Sep 2020 23:14:45
User entered 'No (N)'	System	09 Sep 2020 23:14:45

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T18:14:44', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'c520ef2d-529d-4515-8f6a-f6d140544241'	System	09 Sep 2020 23:14:45
User entered '09 Sep 2020 18:14'	System	09 Sep 2020 23:14:45

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '09 Sep 2020 17:41'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 2'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:12:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-11T00:00:00', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '5ca2b0c8-8227-4820-939b-b8f1b60fddfc'	System	11 Sep 2020 05:00:15
User entered 'Yes (Y)'	System	11 Sep 2020 05:00:15

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:12:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-11T00:00:07', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '5ca2b0c8-8227-4820-939b-b8f1b60fddfc'	System	11 Sep 2020 05:00:15
User entered '97.8'	System	11 Sep 2020 05:00:15

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-11T00:00:10', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '5ca2b0c8-8227-4820-939b-b8f1b60fddfc'	System	11 Sep 2020 05:00:15
User entered 'No (N)'	System	11 Sep 2020 05:00:15

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:12:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-11T00:00:13', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '5ca2b0c8-8227-4820-939b-b8f1b60fddfc'	System	11 Sep 2020 05:00:15
User entered '11 Sep 2020 00:00'	System	11 Sep 2020 05:00:15

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 3'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:12:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T00:01:49', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '3f9b9a9c-abd0-45dc-9a98-0d615ccdbe01'	System	12 Sep 2020 05:02:01
User entered 'Yes (Y)'	System	12 Sep 2020 05:02:01

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:12:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T00:01:54', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '3f9b9a9c-abd0-45dc-9a98-0d615ccdbe01'	System	12 Sep 2020 05:02:01
User entered '98.3'	System	12 Sep 2020 05:02:01

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T00:01:57', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '3f9b9a9c-abd0-45dc-9a98-0d615ccdbe01'	System	12 Sep 2020 05:02:01
User entered 'No (N)'	System	12 Sep 2020 05:02:01

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:12:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T00:01:59', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '3f9b9a9c-abd0-45dc-9a98-0d615ccdbe01'	System	12 Sep 2020 05:02:01
User entered '12 Sep 2020 00:01'	System	12 Sep 2020 05:02:01

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 4'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:12:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T22:13:16', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '266eda56-5b0e-4583-8484-ebd1dc5629aa'	System	13 Sep 2020 03:13:26
User entered 'Yes (Y)'	System	13 Sep 2020 03:13:26

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:12:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T22:13:20', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '266eda56-5b0e-4583-8484-ebd1dc5629aa'	System	13 Sep 2020 03:13:26
User entered '98.7'	System	13 Sep 2020 03:13:26

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T22:13:23', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '266eda56-5b0e-4583-8484-ebd1dc5629aa'	System	13 Sep 2020 03:13:26
User entered 'No (N)'	System	13 Sep 2020 03:13:26

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:12:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T22:13:25', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '266eda56-5b0e-4583-8484-ebd1dc5629aa'	System	13 Sep 2020 03:13:26
User entered '12 Sep 2020 22:13'	System	13 Sep 2020 03:13:26

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 5'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:12:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-13T21:11:01', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '9b536b59-2ee5-4d77-9534-82ea9be3edd1'	System	14 Sep 2020 02:11:18
User entered 'Yes (Y)'	System	14 Sep 2020 02:11:18

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:12:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-13T21:11:04', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '9b536b59-2ee5-4d77-9534-82ea9be3edd1' User entered '98.7'	System	14 Sep 2020 02:11:18
	System	14 Sep 2020 02:11:18

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-13T21:11:08', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '9b536b59-2ee5-4d77-9534-82ea9be3edd1'	System	14 Sep 2020 02:11:18
User entered 'No (N)'	System	14 Sep 2020 02:11:18

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:12:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-13T21:11:10', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '9b536b59-2ee5-4d77-9534-82ea9be3edd1'	System	14 Sep 2020 02:11:18
User entered '13 Sep 2020 21:11'	System	14 Sep 2020 02:11:18

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 6'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:12:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-14T21:18:44', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '28b53fcf-b575-4513-8d19-5a39141d0be6'	System	15 Sep 2020 02:18:57
User entered 'Yes (Y)'	System	15 Sep 2020 02:18:57

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:12:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-14T21:18:48', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '28b53fcf-b575-4513-8d19-5a39141d0be6'	System	15 Sep 2020 02:18:57
User entered '98.6'	System	15 Sep 2020 02:18:57

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-14T21:18:51', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '28b53fcf-b575-4513-8d19-5a39141d0be6'	System	15 Sep 2020 02:18:57
User entered 'No (N)'	System	15 Sep 2020 02:18:57

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:12:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-14T21:18:54', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '28b53fcf-b575-4513-8d19-5a39141d0be6'	System	15 Sep 2020 02:18:57
User entered '14 Sep 2020 21:18'	System	15 Sep 2020 02:18:57

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 7'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:12:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-16T00:02:00', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '42f0e78c-fbbb-4281-8c72-632a770fabd6'	System	16 Sep 2020 05:02:24
User entered 'Yes (Y)'	System	16 Sep 2020 05:02:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:12:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-16T00:02:15', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '42f0e78c-fbbb-4281-8c72-632a770fabd6'	System	16 Sep 2020 05:02:24
User entered '98.6'	System	16 Sep 2020 05:02:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-16T00:02:18', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '42f0e78c-fbbb-4281-8c72-632a770fabd6'	System	16 Sep 2020 05:02:24
User entered 'No (N)'	System	16 Sep 2020 05:02:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:12:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-16T00:02:20', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '42f0e78c-fbbb-4281-8c72-632a770fabd6'	System	16 Sep 2020 05:02:24
User entered '16 Sep 2020 00:02'	System	16 Sep 2020 05:02:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T14:26:50', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '66c8f44d-bc7b-4066-94c6-482febc1095e'	System	09 Sep 2020 19:27:12
User entered 'None (1)'	System	09 Sep 2020 19:27:12

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T14:26:53', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '66c8f44d-bc7b-4066-94c6-482febc1095e'	System	09 Sep 2020 19:27:12
User entered 'No (N)'	System	09 Sep 2020 19:27:12

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T14:26:58', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '66c8f44d-bc7b-4066-94c6-482febc1095e'	System	09 Sep 2020 19:27:12
User entered 'No (N)'	System	09 Sep 2020 19:27:12

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T14:27:05', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '66c8f44d-bc7b-4066-94c6-482febc1095e'	System	09 Sep 2020 19:27:12
User entered 'None (1)'	System	09 Sep 2020 19:27:12

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T14:27:10', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '66c8f44d-bc7b-4066-94c6-482febc1095e'	System	09 Sep 2020 19:27:12
User entered '09 Sep 2020 14:27'	System	09 Sep 2020 19:27:12

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '09 Sep 2020 14:16'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '09 Sep 2020 16:46'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T18:14:49', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'bf99e8c3-6339-4daa-aa87-37fdcc9a6339'	System	09 Sep 2020 23:15:07
User entered 'None (1)'	System	09 Sep 2020 23:15:07

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T18:14:52', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'bf99e8c3-6339-4daa-aa87-37fdcc9a6339'	System	09 Sep 2020 23:15:07
User entered 'No (N)'	System	09 Sep 2020 23:15:07

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T18:14:54', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'bf99e8c3-6339-4daa-aa87-37fdcc9a6339'	System	09 Sep 2020 23:15:07
User entered 'No (N)'	System	09 Sep 2020 23:15:07

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T18:15:02', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'bf99e8c3-6339-4daa-aa87-37fdcc9a6339'	System	09 Sep 2020 23:15:07
User entered 'None (1)'	System	09 Sep 2020 23:15:07

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T18:15:04', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'bf99e8c3-6339-4daa-aa87-37fdcc9a6339'	System	09 Sep 2020 23:15:07
User entered '09 Sep 2020 18:15'	System	09 Sep 2020 23:15:07

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '09 Sep 2020 17:41'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 2'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:12:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-11T00:00:17', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '67c03c82-67ef-4f0d-9b0a-38ec07ea9336'	System	11 Sep 2020 05:00:29
User entered 'None (1)'	System	11 Sep 2020 05:00:29

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:12:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-11T00:00:20', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '67c03c82-67ef-4f0d-9b0a-38ec07ea9336'	System	11 Sep 2020 05:00:29
User entered 'No (N)'	System	11 Sep 2020 05:00:29

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-11T00:00:22', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '67c03c82-67ef-4f0d-9b0a-38ec07ea9336'	System	11 Sep 2020 05:00:29
User entered 'No (N)'	System	11 Sep 2020 05:00:29

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:12:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-11T00:00:24', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '67c03c82-67ef-4f0d-9b0a-38ec07ea9336'	System	11 Sep 2020 05:00:29
User entered 'None (1)'	System	11 Sep 2020 05:00:29

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:12:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-11T00:00:27', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '67c03c82-67ef-4f0d-9b0a-38ec07ea9336'	System	11 Sep 2020 05:00:29
User entered '11 Sep 2020 00:00'	System	11 Sep 2020 05:00:29

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 3'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:12:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T00:02:03', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'cc644c2a-8647-492c-87bf-e392783da3ac'	System	12 Sep 2020 05:02:15
User entered 'None (1)'	System	12 Sep 2020 05:02:15

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:12:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T00:02:05', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'cc644c2a-8647-492c-87bf-e392783da3ac'	System	12 Sep 2020 05:02:15
User entered 'No (N)'	System	12 Sep 2020 05:02:15

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T00:02:08', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'cc644c2a-8647-492c-87bf-e392783da3ac'	System	12 Sep 2020 05:02:15
User entered 'No (N)'	System	12 Sep 2020 05:02:15

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:12:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T00:02:11', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'cc644c2a-8647-492c-87bf-e392783da3ac'	System	12 Sep 2020 05:02:15
User entered 'None (1)'	System	12 Sep 2020 05:02:15

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:12:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T00:02:13', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'cc644c2a-8647-492c-87bf-e392783da3ac'	System	12 Sep 2020 05:02:15
User entered '12 Sep 2020 00:02'	System	12 Sep 2020 05:02:15

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 4'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:12:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T22:13:28', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '4c102ec0-22d4-49c0-baef-b1d13ff2ae2e'	System	13 Sep 2020 03:13:39
User entered 'None (1)'	System	13 Sep 2020 03:13:39

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:12:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T22:13:30', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '4c102ec0-22d4-49c0-baef-b1d13ff2ae2e'	System	13 Sep 2020 03:13:39
User entered 'No (N)'	System	13 Sep 2020 03:13:39

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T22:13:32', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '4c102ec0-22d4-49c0-baef-b1d13ff2ae2e'	System	13 Sep 2020 03:13:39
User entered 'No (N)'	System	13 Sep 2020 03:13:39

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:12:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T22:13:33', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '4c102ec0-22d4-49c0-baef-b1d13ff2ae2e'	System	13 Sep 2020 03:13:39
User entered 'None (1)'	System	13 Sep 2020 03:13:39

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:12:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T22:13:35', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '4c102ec0-22d4-49c0-baef-b1d13ff2ae2e'	System	13 Sep 2020 03:13:39
User entered '12 Sep 2020 22:13'	System	13 Sep 2020 03:13:39

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 5'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:12:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-13T21:11:14', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '42c17f27-bd81-4a39-b1c2-d1edae7b1b02'	System	14 Sep 2020 02:11:26
User entered 'None (1)'	System	14 Sep 2020 02:11:26

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:12:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-13T21:11:17', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '42c17f27-bd81-4a39-b1c2-d1edae7b1b02'	System	14 Sep 2020 02:11:26
User entered 'No (N)'	System	14 Sep 2020 02:11:26

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-13T21:11:20', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '42c17f27-bd81-4a39-b1c2-d1edae7b1b02'	System	14 Sep 2020 02:11:26
User entered 'No (N)'	System	14 Sep 2020 02:11:26

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:12:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-13T21:11:22', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '42c17f27-bd81-4a39-b1c2-d1edae7b1b02'	System	14 Sep 2020 02:11:26
User entered 'None (1)'	System	14 Sep 2020 02:11:26

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:12:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-13T21:11:24', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '42c17f27-bd81-4a39-b1c2-d1edae7b1b02'	System	14 Sep 2020 02:11:26
User entered '13 Sep 2020 21:11'	System	14 Sep 2020 02:11:26

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 6'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:12:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-14T21:18:57', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'dc49ca5d-d09b-420b-9b51-49abea55cd7c'	System	15 Sep 2020 02:19:08
User entered 'None (1)'	System	15 Sep 2020 02:19:08

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:12:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-14T21:18:59', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'dc49ca5d-d09b-420b-9b51-49abea55cd7c'	System	15 Sep 2020 02:19:08
User entered 'No (N)'	System	15 Sep 2020 02:19:08

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-14T21:19:01', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'dc49ca5d-d09b-420b-9b51-49abea55cd7c'	System	15 Sep 2020 02:19:08
User entered 'No (N)'	System	15 Sep 2020 02:19:08

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:12:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-14T21:19:03', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'dc49ca5d-d09b-420b-9b51-49abea55cd7c'	System	15 Sep 2020 02:19:08
User entered 'None (1)'	System	15 Sep 2020 02:19:08

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:12:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-14T21:19:05', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'dc49ca5d-d09b-420b-9b51-49abea55cd7c'	System	15 Sep 2020 02:19:08
User entered '14 Sep 2020 21:19'	System	15 Sep 2020 02:19:08

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 7'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:12:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-16T00:02:24', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'ee720623-022c-4705-b223-5b43dde96e10'	System	16 Sep 2020 05:02:38
User entered 'None (1)'	System	16 Sep 2020 05:02:38

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:12:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-16T00:02:27', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'ee720623-022c-4705-b223-5b43dde96e10'	System	16 Sep 2020 05:02:38
User entered 'No (N)'	System	16 Sep 2020 05:02:38

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-16T00:02:29', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'ee720623-022c-4705-b223-5b43dde96e10'	System	16 Sep 2020 05:02:38
User entered 'No (N)'	System	16 Sep 2020 05:02:38

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:12:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-16T00:02:30', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'ee720623-022c-4705-b223-5b43dde96e10'	System	16 Sep 2020 05:02:38
User entered 'None (1)'	System	16 Sep 2020 05:02:38

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:12:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-16T00:02:33', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'ee720623-022c-4705-b223-5b43dde96e10'	System	16 Sep 2020 05:02:38
User entered '16 Sep 2020 00:02'	System	16 Sep 2020 05:02:38

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T14:27:25', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'b3cb3a82-2289-4620-90ed-6865a530c5ce'	System	09 Sep 2020 19:27:57
User entered 'None (0)'	System	09 Sep 2020 19:27:57

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T14:27:29', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'b3cb3a82-2289-4620-90ed-6865a530c5ce'	System	09 Sep 2020 19:27:57
User entered 'None (0)'	System	09 Sep 2020 19:27:57

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T14:27:33', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'b3cb3a82-2289-4620-90ed-6865a530c5ce'	System	09 Sep 2020 19:27:57
User entered 'None (0)'	System	09 Sep 2020 19:27:57

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T14:27:37', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'b3cb3a82-2289-4620-90ed-6865a530c5ce'	System	09 Sep 2020 19:27:57
User entered 'None (0)'	System	09 Sep 2020 19:27:57

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T14:27:41', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'b3cb3a82-2289-4620-90ed-6865a530c5ce'	System	09 Sep 2020 19:27:57
User entered 'None (0)'	System	09 Sep 2020 19:27:57

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T14:27:44', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'b3cb3a82-2289-4620-90ed-6865a530c5ce'	System	09 Sep 2020 19:27:57
User entered 'None (0)'	System	09 Sep 2020 19:27:57

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T14:27:51', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'b3cb3a82-2289-4620-90ed-6865a530c5ce'	System	09 Sep 2020 19:27:57
User entered 'No (N)'	System	09 Sep 2020 19:27:57

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T14:27:54', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'b3cb3a82-2289-4620-90ed-6865a530c5ce'	System	09 Sep 2020 19:27:57
User entered '09 Sep 2020 14:27'	System	09 Sep 2020 19:27:57

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '09 Sep 2020 14:16'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '09 Sep 2020 16:46'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T18:15:09', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '6f6dca8b-7a62-40be-ac60-3077fcf17e82'	System	09 Sep 2020 23:15:31
User entered 'None (0)'	System	09 Sep 2020 23:15:31

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T18:15:13', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '6f6dca8b-7a62-40be-ac60-3077fcf17e82'	System	09 Sep 2020 23:15:31
User entered 'None (0)'	System	09 Sep 2020 23:15:31

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T18:15:16', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '6f6dca8b-7a62-40be-ac60-3077fcf17e82'	System	09 Sep 2020 23:15:31
User entered 'None (0)'	System	09 Sep 2020 23:15:31

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T18:15:18', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '6f6dca8b-7a62-40be-ac60-3077fcf17e82'	System	09 Sep 2020 23:15:31
User entered 'None (0)'	System	09 Sep 2020 23:15:31

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T18:15:22', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '6f6dca8b-7a62-40be-ac60-3077fcf17e82'	System	09 Sep 2020 23:15:31
User entered 'None (0)'	System	09 Sep 2020 23:15:31

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T18:15:25', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '6f6dca8b-7a62-40be-ac60-3077fcf17e82'	System	09 Sep 2020 23:15:31
User entered 'None (0)'	System	09 Sep 2020 23:15:31

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T18:15:28', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '6f6dca8b-7a62-40be-ac60-3077fcf17e82'	System	09 Sep 2020 23:15:31
User entered 'No (N)'	System	09 Sep 2020 23:15:31

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-09T18:15:30', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '6f6dca8b-7a62-40be-ac60-3077fcf17e82'	System	09 Sep 2020 23:15:31
User entered '09 Sep 2020 18:15'	System	09 Sep 2020 23:15:31

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '09 Sep 2020 17:41'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 2'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-11T00:00:32', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '891c14be-49fe-4f2b-9fb8-c08bd35a2b5f'	System	11 Sep 2020 05:00:55
User entered 'None (0)'	System	11 Sep 2020 05:00:55

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-11T00:00:34', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '891c14be-49fe-4f2b-9fb8-c08bd35a2b5f'	System	11 Sep 2020 05:00:55
User entered 'None (0)'	System	11 Sep 2020 05:00:55

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-11T00:00:36', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '891c14be-49fe-4f2b-9fb8-c08bd35a2b5f'	System	11 Sep 2020 05:00:55
User entered 'None (0)'	System	11 Sep 2020 05:00:55

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-11T00:00:38', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '891c14be-49fe-4f2b-9fb8-c08bd35a2b5f'	System	11 Sep 2020 05:00:55
User entered 'None (0)'	System	11 Sep 2020 05:00:55

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-11T00:00:40', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '891c14be-49fe-4f2b-9fb8-c08bd35a2b5f'	System	11 Sep 2020 05:00:55
User entered 'None (0)'	System	11 Sep 2020 05:00:55

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-11T00:00:42', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '891c14be-49fe-4f2b-9fb8-c08bd35a2b5f'	System	11 Sep 2020 05:00:55
User entered 'None (0)'	System	11 Sep 2020 05:00:55

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-11T00:00:48', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '891c14be-49fe-4f2b-9fb8-c08bd35a2b5f'	System	11 Sep 2020 05:00:55
User entered 'No (N)'	System	11 Sep 2020 05:00:55

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-11T00:00:50', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '891c14be-49fe-4f2b-9fb8-c08bd35a2b5f'	System	11 Sep 2020 05:00:55
User entered '11 Sep 2020 00:00'	System	11 Sep 2020 05:00:55

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 3'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T00:02:17', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'e7de6bba-a750-4d38-94e2-e2a5132f1e5f'	System	12 Sep 2020 05:02:38
User entered 'None (0)'	System	12 Sep 2020 05:02:38

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T00:02:20', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'e7de6bba-a750-4d38-94e2-e2a5132f1e5f'	System	12 Sep 2020 05:02:38
User entered 'None (0)'	System	12 Sep 2020 05:02:38

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T00:02:22', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'e7de6bba-a750-4d38-94e2-e2a5132f1e5f'	System	12 Sep 2020 05:02:38
User entered 'None (0)'	System	12 Sep 2020 05:02:38

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T00:02:24', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'e7de6bba-a750-4d38-94e2-e2a5132f1e5f'	System	12 Sep 2020 05:02:38
User entered 'None (0)'	System	12 Sep 2020 05:02:38

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T00:02:25', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'e7de6bba-a750-4d38-94e2-e2a5132f1e5f'	System	12 Sep 2020 05:02:38
User entered 'None (0)'	System	12 Sep 2020 05:02:38

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T00:02:27', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'e7de6bba-a750-4d38-94e2-e2a5132f1e5f'	System	12 Sep 2020 05:02:38
User entered 'None (0)'	System	12 Sep 2020 05:02:38

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T00:02:31', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'e7de6bba-a750-4d38-94e2-e2a5132f1e5f'	System	12 Sep 2020 05:02:38
User entered 'No (N)'	System	12 Sep 2020 05:02:38

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T00:02:33', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'e7de6bba-a750-4d38-94e2-e2a5132f1e5f'	System	12 Sep 2020 05:02:38
User entered '12 Sep 2020 00:02'	System	12 Sep 2020 05:02:38

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 4'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T22:13:38', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'c24fd05b-8e46-4f85-be09-1dfdeed9265b'	System	13 Sep 2020 03:13:52
User entered 'None (0)'	System	13 Sep 2020 03:13:52

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T22:13:39', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'c24fd05b-8e46-4f85-be09-1dfdeed9265b'	System	13 Sep 2020 03:13:52
User entered 'None (0)'	System	13 Sep 2020 03:13:52

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T22:13:41', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'c24fd05b-8e46-4f85-be09-1dfdeed9265b'	System	13 Sep 2020 03:13:52
User entered 'None (0)'	System	13 Sep 2020 03:13:52

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T22:13:42', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'c24fd05b-8e46-4f85-be09-1dfdeed9265b'	System	13 Sep 2020 03:13:52
User entered 'None (0)'	System	13 Sep 2020 03:13:52

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T22:13:44', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'c24fd05b-8e46-4f85-be09-1dfdeed9265b'	System	13 Sep 2020 03:13:52
User entered 'None (0)'	System	13 Sep 2020 03:13:52

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T22:13:46', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'c24fd05b-8e46-4f85-be09-1dfdeed9265b'	System	13 Sep 2020 03:13:52
User entered 'None (0)'	System	13 Sep 2020 03:13:52

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T22:13:49', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'c24fd05b-8e46-4f85-be09-1dfdeed9265b'	System	13 Sep 2020 03:13:52
User entered 'No (N)'	System	13 Sep 2020 03:13:52

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-12T22:13:50', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'c24fd05b-8e46-4f85-be09-1dfdeed9265b'	System	13 Sep 2020 03:13:52
User entered '12 Sep 2020 22:13'	System	13 Sep 2020 03:13:52

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 5'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-13T21:11:28', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '9b095a9b-2120-4a6e-8062-90a553928302'	System	14 Sep 2020 02:11:43
User entered 'None (0)'	System	14 Sep 2020 02:11:43

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-13T21:11:30', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '9b095a9b-2120-4a6e-8062-90a553928302'	System	14 Sep 2020 02:11:43
User entered 'None (0)'	System	14 Sep 2020 02:11:43

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-13T21:11:31', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '9b095a9b-2120-4a6e-8062-90a553928302'	System	14 Sep 2020 02:11:43
User entered 'None (0)'	System	14 Sep 2020 02:11:43

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-13T21:11:32', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '9b095a9b-2120-4a6e-8062-90a553928302'	System	14 Sep 2020 02:11:43
User entered 'None (0)'	System	14 Sep 2020 02:11:43

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-13T21:11:34', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '9b095a9b-2120-4a6e-8062-90a553928302'	System	14 Sep 2020 02:11:43
User entered 'None (0)'	System	14 Sep 2020 02:11:43

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-13T21:11:36', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '9b095a9b-2120-4a6e-8062-90a553928302'	System	14 Sep 2020 02:11:43
User entered 'None (0)'	System	14 Sep 2020 02:11:43

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-13T21:11:38', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '9b095a9b-2120-4a6e-8062-90a553928302'	System	14 Sep 2020 02:11:43
User entered 'No (N)'	System	14 Sep 2020 02:11:43

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-13T21:11:41', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '9b095a9b-2120-4a6e-8062-90a553928302'	System	14 Sep 2020 02:11:43
User entered '13 Sep 2020 21:11'	System	14 Sep 2020 02:11:43

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 6'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-14T21:19:08', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '0a6f21de-4245-4bce-ba56-729f1bb00250'	System	15 Sep 2020 02:19:24
User entered 'None (0)'	System	15 Sep 2020 02:19:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-14T21:19:09', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '0a6f21de-4245-4bce-ba56-729f1bb00250'	System	15 Sep 2020 02:19:24
User entered 'None (0)'	System	15 Sep 2020 02:19:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-14T21:19:11', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '0a6f21de-4245-4bce-ba56-729f1bb00250'	System	15 Sep 2020 02:19:24
User entered 'None (0)'	System	15 Sep 2020 02:19:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-14T21:19:12', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '0a6f21de-4245-4bce-ba56-729f1bb00250'	System	15 Sep 2020 02:19:24
User entered 'None (0)'	System	15 Sep 2020 02:19:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-14T21:19:14', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '0a6f21de-4245-4bce-ba56-729f1bb00250'	System	15 Sep 2020 02:19:24
User entered 'None (0)'	System	15 Sep 2020 02:19:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-14T21:19:15', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '0a6f21de-4245-4bce-ba56-729f1bb00250'	System	15 Sep 2020 02:19:24
User entered 'None (0)'	System	15 Sep 2020 02:19:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-14T21:19:19', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '0a6f21de-4245-4bce-ba56-729f1bb00250'	System	15 Sep 2020 02:19:24
User entered 'No (N)'	System	15 Sep 2020 02:19:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-14T21:19:22', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '0a6f21de-4245-4bce-ba56-729f1bb00250'	System	15 Sep 2020 02:19:24
User entered '14 Sep 2020 21:19'	System	15 Sep 2020 02:19:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 7'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-16T00:02:40', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '0f637c3d-1bfb-494b-ad48-8efc82001864'	System	16 Sep 2020 05:03:00
User entered 'None (0)'	System	16 Sep 2020 05:03:00

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-16T00:02:42', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '0f637c3d-1bfb-494b-ad48-8efc82001864'	System	16 Sep 2020 05:03:00
User entered 'None (0)'	System	16 Sep 2020 05:03:00

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-16T00:02:44', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '0f637c3d-1bfb-494b-ad48-8efc82001864'	System	16 Sep 2020 05:03:00
User entered 'None (0)'	System	16 Sep 2020 05:03:00

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-16T00:02:46', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '0f637c3d-1bfb-494b-ad48-8efc82001864'	System	16 Sep 2020 05:03:00
User entered 'None (0)'	System	16 Sep 2020 05:03:00

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-16T00:02:47', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '0f637c3d-1bfb-494b-ad48-8efc82001864'	System	16 Sep 2020 05:03:00
User entered 'None (0)'	System	16 Sep 2020 05:03:00

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-16T00:02:49', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '0f637c3d-1bfb-494b-ad48-8efc82001864'	System	16 Sep 2020 05:03:00
User entered 'None (0)'	System	16 Sep 2020 05:03:00

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-16T00:02:54', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '0f637c3d-1bfb-494b-ad48-8efc82001864'	System	16 Sep 2020 05:03:00
User entered 'No (N)'	System	16 Sep 2020 05:03:00

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-09-16T00:02:56', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '0f637c3d-1bfb-494b-ad48-8efc82001864'	System	16 Sep 2020 05:03:00
User entered '16 Sep 2020 00:02'	System	16 Sep 2020 05:03:00

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 19:01:24

US3312573

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 19:01:24

US3312573

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:12:41

US3312573

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:27

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '16 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:12:41

US3312573

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:12:41

US3312573

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4)	29 Sep 2020 17:12:41
	Karol Moore (b) (4)	
	(b) (4)	

US3312573

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:12:44

US3312573

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered '1'	System	29 Sep 2020 17:12:44

US3312573

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:13:05

US3312573

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:27

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '23 Sep 2020'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:13:05

US3312573

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:13:05

US3312573

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4)	29 Sep 2020 17:13:05
	Karol Moore (b) (4)	
	(b) (4)	

US3312573

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:13:08

US3312573

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered '1'	System	29 Sep 2020 17:13:08

US3312573

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Oct 2020 17:00:58

US3312573

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:27

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '30 Sep 2020'	(b) (4) Karol Moore (b) (4)	01 Oct 2020 17:00:58

US3312573

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Oct 2020 17:00:58

US3312573

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4)	01 Oct 2020 17:00:58
	Karol Moore (b) (4)	
	(b) (4)	

US3312573

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Oct 2020 17:01:01

US3312573

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:30:55
User entered '1'	System	01 Oct 2020 17:01:01

US3312573

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:03:31

US3312573

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:03:31

US3312573

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:27

[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 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:03:31

US3312573

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered 'VISIT2'	System	07 Oct 2020 16:03:31

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4)	19 Oct 2020 21:59:05
	(b) (4)	

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '07 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '09:26'	(b) (4) Karol Moore (b) (4)	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered '07 Oct 2020 09:26'	System	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '98.2' F	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Karol Moore (b) (4)	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '67'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered 'bpm'	System	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered 'breaths/min'	System	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '126'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered 'mmHg'	System	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '77'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered 'mmHg'	System	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '07 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '11:31'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered '07 Oct 2020 11:31'	System	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '98.0' F	(b) (4)	19 Oct 2020 21:59:05
	Karol Moore (b) (4)	
	(b) (4)	

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Karol Moore (b) (4)	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '75'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered 'bpm'	System	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered 'breaths/min'	System	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '131'	(b) (4) Karol Moore (b) (4)	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered 'mmHg'	System	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '80'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered 'mmHg'	System	19 Oct 2020 21:59:05

US3312573

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:11

US3312573

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '07 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:11

US3312573

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:27

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	19 Oct 2020 21:59:25

US3312573

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:27

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '07 Oct 2020'	(b) (4) Karol Moore (b) (4)	19 Oct 2020 21:59:25

US3312573

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:27

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Urine (URINE)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:25

US3312573

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:27

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Negative (NEGATIVE)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:25

US3312573

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:27

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	19 Oct 2020 21:59:25

US3312573

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:27

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Karol Moore (b) (4)	19 Oct 2020 21:59:25

US3312573

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:27

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Karol Moore (b) (4)	19 Oct 2020 21:59:25

US3312573

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered empty.	System	19 Oct 2020 21:59:25

US3312573

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:04:19

US3312573

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:27

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:04:19

US3312573

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:04:19

US3312573

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered 'MRNA-1273 OR PLACEBO'	System	07 Oct 2020 16:04:19

US3312573

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:27

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User closed query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 13:42:30
' (Site from DM).		
Query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:36
' answered with 'UPDATED' (Site from DM).		
User entered '07 Oct 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:32
User opened query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	(b) (4), (b) (6)	14 Oct 2020 17:50:23
' (Site from DM).		
User entered '7 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 16:04:19

US3312573

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:27

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '11:00'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:04:19

US3312573

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:27

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered '07 Oct 2020 11:00'	System	19 Oct 2020 21:59:32
User entered '7 Oct 2020 11:00'	System	07 Oct 2020 16:04:19

US3312573

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:27

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:04:19

US3312573

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:27

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered 'ONCE'	System	07 Oct 2020 16:04:19

US3312573

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:27

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered 'INTRAMUSCULAR'	System	07 Oct 2020 16:04:19

US3312573

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	19 Oct 2020 21:59:47

US3312573

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:27

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '07 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:47

US3312573

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:27

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '10:11'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:47

US3312573

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered '07 Oct 2020 10:11'	System	19 Oct 2020 21:59:47

US3312573

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:12:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '07 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:56

US3312573

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:12:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:56

US3312573

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:12:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	19 Oct 2020 21:59:56

US3312573

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:12:27

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered '09:57'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:56

US3312573

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:12:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered '07 Oct 2020 09:57'	System	19 Oct 2020 21:59:56

US3312573

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:12:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:56

US3312573

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:12:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 21:59:56

US3312573

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:12:27

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Karol Moore (b) (4)	19 Oct 2020 21:59:56

US3312573

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:12:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered empty.	System	19 Oct 2020 21:59:56

US3312573

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:04:30

US3312573

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered '1'	System	07 Oct 2020 16:04:30

US3312573

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	07 Oct 2020 16:04:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 16:04:19

US3312573

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-07T11:33:01', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'f5cfd260-66ff-437b-b466-d313f223eea0'	System	07 Oct 2020 16:33:15
User entered 'Yes (Y)'	System	07 Oct 2020 16:33:15

US3312573

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-07T11:33:05', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'f5cfd260-66ff-437b-b466-d313f223eea0'	System	07 Oct 2020 16:33:15
User entered '98.0'	System	07 Oct 2020 16:33:15

US3312573

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-07T11:33:08', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'f5cfd260-66ff-437b-b466-d313f223eea0'	System	07 Oct 2020 16:33:15
User entered 'No (N)'	System	07 Oct 2020 16:33:15

US3312573

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-07T11:33:12', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'f5cfd260-66ff-437b-b466-d313f223eea0'	System	07 Oct 2020 16:33:15
User entered '07 Oct 2020 11:33'	System	07 Oct 2020 16:33:15

US3312573

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '07 Oct 2020 11:20'	System	07 Oct 2020 16:04:19

US3312573

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '07 Oct 2020 13:50'	System	07 Oct 2020 16:04:19

US3312573

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	07 Oct 2020 16:04:19
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 16:04:19

US3312573

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-08T09:52:13', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '8df1aed5-f1b1-48bb-b332-111758945246'	System	08 Oct 2020 14:52:27
User entered 'Yes (Y)'	System	08 Oct 2020 14:52:27

US3312573

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-08T09:52:18', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '8df1aed5-f1b1-48bb-b332-111758945246'	System	08 Oct 2020 14:52:27
User entered '98.3'	System	08 Oct 2020 14:52:27

US3312573

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-08T09:52:20', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '8df1aed5-f1b1-48bb-b332-111758945246'	System	08 Oct 2020 14:52:27
User entered 'No (N)'	System	08 Oct 2020 14:52:27

US3312573

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-08T09:52:23', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '8df1aed5-f1b1-48bb-b332-111758945246'	System	08 Oct 2020 14:52:27
User entered '08 Oct 2020 09:52'	System	08 Oct 2020 14:52:27

US3312573

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '07 Oct 2020 14:45'	System	07 Oct 2020 16:04:19

US3312573

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 16:04:19

US3312573

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	07 Oct 2020 16:04:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 16:04:19

US3312573

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-07T11:33:26', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'b44125a6-9fdb-4c1d-bbc1-53b68c4882ea'	System	07 Oct 2020 16:34:28
User entered 'None (1)'	System	07 Oct 2020 16:34:28

US3312573

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-07T11:33:32', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'b44125a6-9fdb-4c1d-bbc1-53b68c4882ea'	System	07 Oct 2020 16:34:28
User entered 'No (N)'	System	07 Oct 2020 16:34:28

US3312573

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-07T11:33:36', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'b44125a6-9fdb-4c1d-bbc1-53b68c4882ea'	System	07 Oct 2020 16:34:28
User entered 'No (N)'	System	07 Oct 2020 16:34:28

US3312573

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-07T11:33:40', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'b44125a6-9fdb-4c1d-bbc1-53b68c4882ea'	System	07 Oct 2020 16:34:28
User entered 'None (1)'	System	07 Oct 2020 16:34:28

US3312573

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-07T11:33:44', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'b44125a6-9fdb-4c1d-bbc1-53b68c4882ea'	System	07 Oct 2020 16:34:28
User entered '07 Oct 2020 11:33'	System	07 Oct 2020 16:34:28

US3312573

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '07 Oct 2020 11:20'	System	07 Oct 2020 16:04:19

US3312573

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '07 Oct 2020 13:50'	System	07 Oct 2020 16:04:19

US3312573

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	07 Oct 2020 16:04:19
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 16:04:19

US3312573

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-08T09:52:26', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '4d4fd2e3-8fc8-4d45-bf30-d245ffc27d3d'	System	08 Oct 2020 14:52:40
User entered 'None (1)'	System	08 Oct 2020 14:52:40

US3312573

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-08T09:52:29', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '4d4fd2e3-8fc8-4d45-bf30-d245ffc27d3d'	System	08 Oct 2020 14:52:40
User entered 'No (N)'	System	08 Oct 2020 14:52:40

US3312573

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-08T09:52:31', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '4d4fd2e3-8fc8-4d45-bf30-d245ffc27d3d'	System	08 Oct 2020 14:52:40
User entered 'No (N)'	System	08 Oct 2020 14:52:40

US3312573

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-08T09:52:33', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '4d4fd2e3-8fc8-4d45-bf30-d245ffc27d3d'	System	08 Oct 2020 14:52:40
User entered 'None (1)'	System	08 Oct 2020 14:52:40

US3312573

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-08T09:52:35', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '4d4fd2e3-8fc8-4d45-bf30-d245ffc27d3d'	System	08 Oct 2020 14:52:40
User entered '08 Oct 2020 09:52'	System	08 Oct 2020 14:52:40

US3312573

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '07 Oct 2020 14:45'	System	07 Oct 2020 16:04:19

US3312573

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 16:04:19

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	07 Oct 2020 16:04:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 16:04:19

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-07T11:33:50', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '0156c68c-98d5-4d61-99a1-e71f4e051047'	System	07 Oct 2020 16:34:30
User entered 'None (0)'	System	07 Oct 2020 16:34:30

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-07T11:33:53', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '0156c68c-98d5-4d61-99a1-e71f4e051047'	System	07 Oct 2020 16:34:30
User entered 'None (0)'	System	07 Oct 2020 16:34:30

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-07T11:33:56', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '0156c68c-98d5-4d61-99a1-e71f4e051047'	System	07 Oct 2020 16:34:30
User entered 'None (0)'	System	07 Oct 2020 16:34:30

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-07T11:33:59', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '0156c68c-98d5-4d61-99a1-e71f4e051047'	System	07 Oct 2020 16:34:30
User entered 'None (0)'	System	07 Oct 2020 16:34:30

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-07T11:34:01', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '0156c68c-98d5-4d61-99a1-e71f4e051047'	System	07 Oct 2020 16:34:30
User entered 'None (0)'	System	07 Oct 2020 16:34:30

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-07T11:34:04', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '0156c68c-98d5-4d61-99a1-e71f4e051047'	System	07 Oct 2020 16:34:30
User entered 'None (0)'	System	07 Oct 2020 16:34:30

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-07T11:34:06', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '0156c68c-98d5-4d61-99a1-e71f4e051047'	System	07 Oct 2020 16:34:30
User entered 'No (N)'	System	07 Oct 2020 16:34:30

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-07T11:34:10', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: '0156c68c-98d5-4d61-99a1-e71f4e051047'	System	07 Oct 2020 16:34:30
User entered '07 Oct 2020 11:34'	System	07 Oct 2020 16:34:30

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '07 Oct 2020 11:20'	System	07 Oct 2020 16:04:19

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '07 Oct 2020 13:50'	System	07 Oct 2020 16:04:19

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
Data entry locked.	System	07 Oct 2020 16:04:19
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 16:04:19

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-08T09:52:38', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'bee76d7a-b9f2-430d-a824-7730d66ce98a'	System	08 Oct 2020 14:52:56
User entered 'None (0)'	System	08 Oct 2020 14:52:56

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-08T09:52:39', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'bee76d7a-b9f2-430d-a824-7730d66ce98a'	System	08 Oct 2020 14:52:56
User entered 'None (0)'	System	08 Oct 2020 14:52:56

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-08T09:52:41', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'bee76d7a-b9f2-430d-a824-7730d66ce98a'	System	08 Oct 2020 14:52:56
User entered 'None (0)'	System	08 Oct 2020 14:52:56

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-08T09:52:42', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'bee76d7a-b9f2-430d-a824-7730d66ce98a'	System	08 Oct 2020 14:52:56
User entered 'None (0)'	System	08 Oct 2020 14:52:56

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-08T09:52:43', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'bee76d7a-b9f2-430d-a824-7730d66ce98a'	System	08 Oct 2020 14:52:56
User entered 'None (0)'	System	08 Oct 2020 14:52:56

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-08T09:52:45', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'bee76d7a-b9f2-430d-a824-7730d66ce98a'	System	08 Oct 2020 14:52:56
User entered 'None (0)'	System	08 Oct 2020 14:52:56

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-08T09:52:49', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'bee76d7a-b9f2-430d-a824-7730d66ce98a'	System	08 Oct 2020 14:52:56
User entered 'No (N)'	System	08 Oct 2020 14:52:56

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5714baf510fa566a)', Time: '2020-10-08T09:52:50', User OID: 'PatientReportedOutcome (US3312573)', ODM File OID: 'bee76d7a-b9f2-430d-a824-7730d66ce98a'	System	08 Oct 2020 14:52:56
User entered '08 Oct 2020 09:52'	System	08 Oct 2020 14:52:56

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '07 Oct 2020 14:45'	System	07 Oct 2020 16:04:19

US3312573

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:12:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:09:10
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 16:04:19

US3312573

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:10:09
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:22:00

US3312573

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:10:09
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	18 Mar 2021 20:05:20
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	17 Dec 2020 19:55:52
User entered '14 Oct 2020'	Kelly Moen (b) (4)	11 Dec 2020 19:22:00
	(b) (4)	

US3312573

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:10:09
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Kelly Moen (b) (4)	11 Dec 2020 19:22:00

US3312573

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:10:09
User entered 'message left on 10/14, 10/15 and 10/16. Subject did not return call.'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:22:00

US3312573

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:22:08

US3312573

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered '1'	System	11 Dec 2020 19:22:08

US3312573

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:10:09
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:25:02

US3312573

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:10:09
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	18 Mar 2021 20:05:20
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	17 Dec 2020 19:55:52
User entered '21 Oct 2020'	Kelly Moen (b) (4)	11 Dec 2020 19:25:02
	(b) (4)	

US3312573

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:10:09
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:25:02

US3312573

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:10:09
User entered 'message left on 10/21, 10/22, and 10/23. Subject did not return call.'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:25:02

US3312573

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:25:10

US3312573

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered '1'	System	11 Dec 2020 19:25:10

US3312573

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:10:09
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:26:10

US3312573

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:10:09
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	18 Mar 2021 20:05:20
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	17 Dec 2020 19:55:52
User entered '28 Oct 2020'	Kelly Moen (b) (4)	11 Dec 2020 19:26:10
	(b) (4)	

US3312573

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:10:09
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Kelly Moen (b) (4)	11 Dec 2020 19:26:10

US3312573

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:10:09
User entered 'message left on 10/28, 10/29, and 10/30. Subject did not return call.'	Kelly Moen (b) (4)	11 Dec 2020 19:26:10

US3312573

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:26:22

US3312573

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered '1'	System	11 Dec 2020 19:26:22

US3312573

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:26:46

US3312573

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:26:46

US3312573

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:27

[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 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:26:46

US3312573

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered 'VISIT3'	System	11 Dec 2020 19:26:46

US3312573

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:39:04

US3312573

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:39:04

US3312573

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:39:04

US3312573

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered empty.	System	11 Dec 2020 19:39:04

US3312573

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:39:04

US3312573

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:39:04

US3312573

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:39:04

US3312573

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:39:04

US3312573

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered empty.	System	11 Dec 2020 19:39:04

US3312573

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:39:04

US3312573

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered empty.	System	11 Dec 2020 19:39:04

US3312573

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:39:04

US3312573

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered empty.	System	11 Dec 2020 19:39:04

US3312573

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:39:04

US3312573

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered empty.	System	11 Dec 2020 19:39:04

US3312573

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04

US3312573

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:27

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04

US3312573

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:39:10

US3312573

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:27

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:39:10

US3312573

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:39:15

US3312573

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:39:15

US3312573

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:27

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:39:15

US3312573

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered empty.	System	11 Dec 2020 19:39:15

US3312573

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:58:02
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Dec 2020 19:28:29

US3312573

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered empty.	System	11 Dec 2020 19:28:29

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 64'	System	09 Sep 2020 19:01:24

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[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 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Have you been exposed to someone with 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 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47
Data entry locked.	System	09 Sep 2020 19:01:24
User entered '09 Nov 2020 00:01'	System	09 Sep 2020 19:01:24

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47
Data entry locked.	System	09 Sep 2020 19:01:24
User entered '13 Nov 2020 23:59'	System	09 Sep 2020 19:01:24

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47
Data entry locked.	System	09 Sep 2020 19:01:24
User entered 'Day 71'	System	09 Sep 2020 19:01:24

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[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 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Have you been exposed to someone with 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 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47
Data entry locked.	System	09 Sep 2020 19:01:24
User entered '16 Nov 2020 00:01'	System	09 Sep 2020 19:01:24

US3312573

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:41:47
Data entry locked.	System	09 Sep 2020 19:01:24
User entered '20 Nov 2020 23:59'	System	09 Sep 2020 19:01:24

US3312573

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:12:27

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:10:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:03:32

US3312573

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:12:27

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:13:15

US3312573

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: ETONOGESTREL, PRODUCTSYNONYM: NEXPLANON - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Nov 2020 19:39:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Nov 2020 19:39:14
Data point term sent to Coder Coding entries removed.	System Karol Moore (b) (4)	25 Nov 2020 19:39:00 25 Nov 2020 19:38:03
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: ETONOGESTREL, PRODUCTSYNONYM: NEXPLANON - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Sep 2020 17:14:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Sep 2020 17:14:43
Data point term sent to Coder User entered 'NEXPLANON'	System Karol Moore (b) (4)	29 Sep 2020 17:14:14 29 Sep 2020 17:13:55

US3312573

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User closed query 'Per DM CLR: Indication for medication is reportd as BIRTH CONTROL, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 05:25:36
Query 'Per DM CLR: Indication for medication is reportd as BIRTH CONTROL, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	24 Nov 2020 17:42:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	24 Nov 2020 17:42:53
User opened query 'Per DM CLR: Indication for medication is reportd as BIRTH CONTROL, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 08:49:38
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:13:55

US3312573

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User entered 'BIRTH CONTROL'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:13:55

US3312573

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User entered '1'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:13:55

US3312573

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User entered 'Other (OTHER)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:13:55

US3312573

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:27

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User entered 'IMPANT'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:13:55

US3312573

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User entered 'other (OTHER)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:13:55

US3312573

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User entered 'ONCE EVERY 3 YEARS'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:13:55

US3312573

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User entered 'Other (OTHER)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:13:55

US3312573

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 06:28:50
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	25 Nov 2020 19:38:07
User entered 'SUBDERMAL' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	25 Nov 2020 19:38:03
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 09:23:38
User entered 'INTRADERMAL'	Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:13:55

US3312573

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User entered 'UN Jan 2019'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:13:55

US3312573

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:13:55

US3312573

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:13:55

US3312573

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User entered empty.	(b) (4) Karol Moore (b) (4)	29 Sep 2020 17:13:55

US3312573

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	29 Sep 2020 17:13:55

US3312573

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered empty.	System	29 Sep 2020 17:13:55

US3312573

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered empty.	System	29 Sep 2020 17:13:55

US3312573

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:12:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User entered empty.	System	29 Sep 2020 17:13:55

US3312573

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:12:27

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:13:04
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:10:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:04:19

US3312573

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:12:27

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:00:16
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 13:02:02
Query 'Data is required. Please complete.' answered with 'Subject received both doses' (Site from System).	Kelly Moen (b) (4) (b) (4)	09 Dec 2020 16:08:17
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 16:07:47
User entered empty; reason for change Data Entry Error	Kelly Moen (b) (4) (b) (4)	09 Dec 2020 16:07:47
User entered '31 Oct 2020'	Kelly Moen (b) (4) (b) (4)	09 Dec 2020 16:04:21

US3312573

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:12:27

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:00:16
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 13:01:54
Query 'Data is required. Please complete.' answered with 'Subject received both doses' (Site from System).	Kelly Moen (b) (4) (b) (4)	09 Dec 2020 16:08:20
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 16:07:47
User entered empty; reason for change Data Entry Error	Kelly Moen (b) (4) (b) (4)	09 Dec 2020 16:07:47
User entered 'Lost To Follow-up (LOST TO FOLLOW-UP)'	Kelly Moen (b) (4) (b) (4)	09 Dec 2020 16:04:21

US3312573

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:12:27

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 12:00:16
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	09 Dec 2020 16:04:21

US3312573

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:12:27

[Date of study discontinuation/completion \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:00:16
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:10:09
User entered '31 Oct 2020' reason for change: Data Entry Error	(b) (4)	18 Mar 2021 20:05:53
Signature has been broken.	Kelly Moen (b) (4)	18 Mar 2021 20:05:20
User entered '12 Nov 2020' reason for change: Data Entry Error	(b) (4)	18 Mar 2021 20:05:20
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4)	17 Dec 2020 19:55:52
User entered '31 Oct 2020'	Monica Atwood (b) (4)	09 Dec 2020 16:08:45
	Kelly Moen (b) (4)	
	(b) (4)	

US3312573

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:12:27

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:00:16
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User closed query 'Per CDM-Reason for discontinuation is recored as 'Lost To Follow-up',however,no data is recorded on 'Dosing discontinuation form'.Kindly consider to verify and update data accordingly else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 13:27:28
User closed query 'Per CDM- If participant was lost to follow-up, use date of last direct contact (e.g., clinic visit or phone call) with the participant. Kindly review and confirm to update correct last date of contact else clarify.Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 13:27:22
Query 'Per CDM- If participant was lost to follow-up, use date of last direct contact (e.g., clinic visit or phone call) with the participant. Kindly review and confirm to update correct last date of contact else clarify.Thank you.' answered with 'updated to last date of subject contact' (Site from DM).	Monica Atwood (b) (4) (b) (4)	17 Dec 2020 19:56:45
Query 'Per CDM-Reason for discontinuation is recored as 'Lost To Follow-up',however,no data is recorded on 'Dosing discontinuation form'.Kindly consider to verify and update data accordingly else clarify.' answered with 'dosing was not discontinued, subject received both doses prior to Lost to follow up' (Site from DM).	Monica Atwood (b) (4) (b) (4)	17 Dec 2020 19:49:20
User opened query 'Per CDM- If participant was lost to follow-up, use date of last direct contact (e.g., clinic visit or phone call) with the participant. Kindly review and confirm to update correct last date of contact else clarify.Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 07:12:18
User opened query 'Per CDM-Reason for discontinuation is recored as 'Lost To Follow-up',however,no data is recorded on 'Dosing discontinuation form'.Kindly consider to verify and update data accordingly else clarify.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 07:12:10
User entered 'Lost To Follow-up (LOST TO FOLLOW-UP)'	Kelly Moen (b) (4) (b) (4)	09 Dec 2020 16:08:45

US3312573

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:12:27

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 12:00:16
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	09 Dec 2020 16:08:45

US3312573

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:12:27

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:00:16
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	09 Dec 2020 16:08:45

US3312573

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:12:27

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:00:16
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	09 Dec 2020 16:08:45

US3312573

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:12:27

[Date of death \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:00:16
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	09 Dec 2020 16:08:45

US3312573

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:12:27

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:00:16
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:36:10
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	09 Dec 2020 16:08:45