

US3312187 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

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US3312187

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 20:58:57

Generated On: 09 Jun 2021 17:00:21

Participant ID

US3312187

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

US3312187

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Date of Birth (MMM yyyy)	(b) (6) 1989
Age	31
Age Units	YEARS
Age (Derived)	31
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Date of Informed Consent (<i>dd MMM yyyy</i>)	20 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 22:05:22

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 22:05:22

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Were any significant conditions reported?

Yes ☐

No ☒

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:05:22

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	20 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:05 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 11:05
Height (<i>xxx.x</i>)	69 in
Weight (<i>xxx.x</i>)	205 lb
BMI (<i>xxx.x</i>)	30.33651 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:05:22

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 22:05:22

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Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☒ No ☐

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 22:05:22

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	20 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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US3312187

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 106436

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	11:05 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 11:05
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	12:33 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 12:33
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

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.

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

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) 20 AUG 2020

What was the treatment time? (00:00-23:59) 12:02 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 12:02

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 AUG 2020
Collection time (00:00-23:59)	11:28 (24 HR)
Collection date and time (derived)	20 AUG 2020 11:28

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Collection date (dd MMM yyyy)			20 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:24	20 AUG 2020 11:24
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

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

98.3 °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

20 AUG 2020 12:36

PC Open Date & Time

20 AUG 2020 12:22

PC Close Date & Time

20 AUG 2020 14:52

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.3 °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	20 AUG 2020 18:02
PC Open Date & Time	20 AUG 2020 15:47
PC Close Date & Time	21 AUG 2020 11:59

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:00:21

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 19:45

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:21

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

22 AUG 2020 16:24

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 19:45

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 17:10

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 17:33

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

26 AUG 2020 14:49

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

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

20 AUG 2020 12:37

PC Open Date & Time

20 AUG 2020 12:22

PC Close Date & Time

20 AUG 2020 14:52

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

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

20 AUG 2020 18:03

PC Open Date & Time

20 AUG 2020 15:47

PC Close Date & Time

21 AUG 2020 11:59

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:00:21

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

21 AUG 2020 19:46

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:21

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

22 AUG 2020 16:25

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:21

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

23 AUG 2020 19:45

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:21

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

24 AUG 2020 17:10

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:21

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

25 AUG 2020 17:33

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:21

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

26 AUG 2020 14:50

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

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 ☐

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 12:37
PC Open Date & Time	20 AUG 2020 12:22
PC Close Date & Time	20 AUG 2020 14:52

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Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

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 ☐

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 18:03
PC Open Date & Time	20 AUG 2020 15:47
PC Close Date & Time	21 AUG 2020 11:59

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

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 ☒

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 19:46
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 16:25
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

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 ☒

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 19:46
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

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 ☒

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 17:10
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 17:33
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

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 ☒

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 14:50
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3312187

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312187

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312187

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3312187

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312187

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312187

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312187

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	17 SEP 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	08:09 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 08:09
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	09:20 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 09:20
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	49 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3312187

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

US3312187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

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) 17 SEP 2020

What was the treatment time? (00:00-23:59) 08:50 (24 HR)

Treatment Date and Time (derived) 17 SEP 2020 08:50

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

US3312187

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 SEP 2020
Collection time (00:00-23:59)	08:27 (24 HR)
Collection date and time (derived)	17 SEP 2020 08:27

US3312187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:24	17 SEP 2020 08:24
Nasopharyngeal Swab 2	No		

US3312187

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 09:24

PC Open Date & Time

17 SEP 2020 09:10

PC Close Date & Time

17 SEP 2020 11:40

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	17 SEP 2020 22:39
PC Open Date & Time	17 SEP 2020 12:35
PC Close Date & Time	18 SEP 2020 11:59

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 19:10

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:21

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 22:44

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

20 SEP 2020 16:57

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

21 SEP 2020 23:59

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

22 SEP 2020 22:20

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

23 SEP 2020 16:48

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

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

17 SEP 2020 09:24

PC Open Date & Time

17 SEP 2020 09:10

PC Close Date & Time

17 SEP 2020 11:40

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

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

17 SEP 2020 22:40

PC Open Date & Time

17 SEP 2020 12:35

PC Close Date & Time

18 SEP 2020 11:59

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:00:21

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

18 SEP 2020 19:10

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:21

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

19 SEP 2020 22:44

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:21

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

20 SEP 2020 16:57

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:21

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

21 SEP 2020 23:59

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:21

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

22 SEP 2020 22:20

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:21

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

23 SEP 2020 16:48

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

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 ☐

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 09:24
PC Open Date & Time	17 SEP 2020 09:10
PC Close Date & Time	17 SEP 2020 11:40

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

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 ☐

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 22:40
PC Open Date & Time	17 SEP 2020 12:35
PC Close Date & Time	18 SEP 2020 11:59

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

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 ☒

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 19:10
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 22:45
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

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)

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US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 16:57
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

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

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EAB) (1725)

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 23:59
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

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
EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 22:20
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

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 ☒

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 16:48
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3312187

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312187

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312187

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 01 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3312187

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312187

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3312187

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312187

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:05:23

Generated On: 09 Jun 2021 17:00:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3312187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:05:23

Generated On: 09 Jun 2021 17:00:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	08:10 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 08:10
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312187

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:05:23

Generated On: 09 Jun 2021 17:00:21

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.

US3312187

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:05:23

Generated On: 09 Jun 2021 17:00:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 OCT 2020

Collection time (00:00-23:59)

08:50 (24 HR)

Collection date and time (derived)

15 OCT 2020 08:50

US3312187

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:05:22

Generated On: 09 Jun 2021 17:00:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 OCT 2020 00:01:24
Patient Cloud Open Date & Time	20 OCT 2020 00:01
Patient Cloud Close Date & Time	24 OCT 2020 23:59

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 71

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

27 OCT 2020 12:43:43

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 NOV 2020 00:01:38
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with 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 <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	17 NOV 2020 10:19:06
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 103

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

01 DEC 2020 00:01:30

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 110

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

08 DEC 2020 13:15:40

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 117

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

12 DEC 2020 00:01:18

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 124

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 00:01:41

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 131

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 00:01:29

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 138

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 23:05:13

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 145

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

09 JAN 2021 00:01:12

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 152

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 00:01:30

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 159

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 00:03:33

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 166

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 00:01:34

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 173

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 06:11:53

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 00:02:26
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 187

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 00:01:13

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 194

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 02:06:56

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 MAR 2021 10:31:00
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 208

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 08:08:40

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 215

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 00:03:37

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 222

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 00:03:26

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 APR 2021 09:43:28
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 APR 2021 14:48:59
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 243

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 00:01:32

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 APR 2021 00:02:46
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 257

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 00:02:16

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 271

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 MAY 2021 00:01
Patient Cloud Close Date & Time	19 MAY 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 MAY 2021 00:01
Patient Cloud Close Date & Time	26 MAY 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 299

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 306

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

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

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

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

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

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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 313

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2021 00:01
Patient Cloud Close Date & Time	14 JUL 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 334

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 341

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 JUL 2021 00:01
Patient Cloud Close Date & Time	28 JUL 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 355

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 362

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 369

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 376

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 383

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 390

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 397

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 404

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

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

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

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

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

Fever (Temperature \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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 418

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 425

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

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

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

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

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

Fever (Temperature \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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 432

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 OCT 2021 00:01
Patient Cloud Close Date & Time	27 OCT 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 446

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 NOV 2021 00:01
Patient Cloud Close Date & Time	17 NOV 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 474

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 481

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 495

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	25 DEC 2021 00:01
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Patient Cloud Close Date & Time	29 DEC 2021 23:59
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US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 502

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 509

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 516

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 523

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

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

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

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

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

Fever (Temperature \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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 530

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 537

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 544

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 551

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 558

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 565

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 572

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 MAR 2022 00:01
Patient Cloud Close Date & Time	16 MAR 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 579

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 586

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

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

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

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

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

Fever (Temperature \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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 593

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 APR 2022 00:01
Patient Cloud Close Date & Time	13 APR 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 628

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 642

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 649

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 656

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

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

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

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

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

Fever (Temperature \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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 663

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 677

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 684

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 698

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 705

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 712

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 726

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 AUG 2022 00:01
Patient Cloud Close Date & Time	17 AUG 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 733

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	10 SEP 2022 00:01
Patient Cloud Close Date & Time	14 SEP 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 761

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

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

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

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

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

Fever (Temperature \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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	17 SEP 2022 00:01
Patient Cloud Close Date & Time	21 SEP 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 775

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 782

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

DAY 789

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2022 00:01
Patient Cloud Close Date & Time	26 OCT 2022 23:59

US3312187

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:00:21

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 02:07:03

US3312187

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3312187

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312187

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312187

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312187

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312187

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312187

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312187

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312187

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 20:59:37

Generated On: 09 Jun 2021 17:00:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	24 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3312187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 20:59:37

Generated On: 09 Jun 2021 17:00:21

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) _____

US3312187

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 20:59:37

Generated On: 09 Jun 2021 17:00:21

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.

US3312187

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 MAR 2021
Collection time (00:00-23:59)	08:32 (24 HR)
Collection date and time (derived)	24 MAR 2021 08:32

US3312187

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312187

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 20:39:51

Generated On: 09 Jun 2021 17:00:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312187

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 20:39:51

Generated On: 09 Jun 2021 17:00:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312187

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312187

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312187

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:00:21

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3312187

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:00:21

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3312187

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	27 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3312187

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 20:58:57

Generated On: 09 Jun 2021 17:00:21

Date of updated informed consent (<i>dd MMM yyyy</i>)	27 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	27 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3312187

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

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

US3312187

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 JAN 2021
Time of assessment (00:00-23:59)	13:53 (24 HR)
Vital Signs Date and Time (derived)	27 JAN 2021 13:53
Temperature (xxx.x)	99.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
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)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3312187

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 JAN 2021
Time of assessment (00:00-23:59)	15:19 (24 HR)
Vital Signs Date and Time (derived)	27 JAN 2021 15:19
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3312187

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

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 20:58:57

Generated On: 09 Jun 2021 17:00:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 JAN 2021

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

US3312187

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

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 20:58:57

Generated On: 09 Jun 2021 17:00:21

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 27 JAN 2021

What was the treatment time? (00:00-23:59) 14:48 (24 HR)

Treatment Date and Time (derived) 27 JAN 2021 14:48

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

US3312187

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 20:58:57

Generated On: 09 Jun 2021 17:00:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	27 JAN 2021
-------------------------------	-------------

Collection time (00:00-23:59)	13:35 (24 HR)
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Collection date and time (derived)	27 JAN 2021 13:35
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US3312187

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 20:58:57

Generated On: 09 Jun 2021 17:00:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 JAN 2021
Collection time (00:00 - 23:59)	13:34
Collection Date and Time (derived)	27 JAN 2021 13:34

US3312187

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

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 20:58:57

Generated On: 09 Jun 2021 17:00:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312187

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312187

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3312187

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 20:58:57

Generated On: 09 Jun 2021 17:00:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 20:58:57

Generated On: 09 Jun 2021 17:00:21

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 FEB 2021
Time of assessment (00:00-23:59)	08:51 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 08:51
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 20:58:57

Generated On: 09 Jun 2021 17:00:21

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 FEB 2021
Time of assessment (00:00-23:59)	10:16 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 10:16
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3312187

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 20:58:57

Generated On: 09 Jun 2021 17:00:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 FEB 2021

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

US3312187

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 20:58:57

Generated On: 09 Jun 2021 17:00:21

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 24 FEB 2021

What was the treatment time? (00:00-23:59) 09:45 (24 HR)

Treatment Date and Time (derived) 24 FEB 2021 09:45

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

US3312187

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 20:58:57

Generated On: 09 Jun 2021 17:00:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312187

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 03 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3312187

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312187

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 20:58:57

Generated On: 09 Jun 2021 17:00:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3312187

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 20:58:57

Generated On: 09 Jun 2021 17:00:21

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) _____

US3312187

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 20:58:57

Generated On: 09 Jun 2021 17:00:21

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.

US3312187

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 20:58:57

Generated On: 09 Jun 2021 17:00:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 MAR 2021
Collection time (00:00-23:59)	08:32 (24 HR)
Collection date and time (derived)	24 MAR 2021 08:32

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

Visit Date	17 SEP 2020
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Please check all assessments that apply for this visit

Physical Exam	False
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Vital Signs	True
-------------	------

Immunogenicity Assessment	False
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Pregnancy Test	False
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US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	08:14 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 08:14
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

Visit Date	17 SEP 2020
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	09:25 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 09:25
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312187

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 15:50:13

Generated On: 09 Jun 2021 17:00:21

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 15:50:13

Generated On: 09 Jun 2021 17:00:21

AEID	USA-US300-2020-MRNA-1273-P30 1000014
Adverse event	RHABDOMYOLISIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	08 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	12 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	14 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 15:50:13

Generated On: 09 Jun 2021 17:00:21

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 15:50:13

Generated On: 09 Jun 2021 17:00:21

31 YEAR OLD MALE, NO
SIGNIFICANT MEDICAL
HISTORY, (b) (6)
SOCCER COACH, DOSED
20AUG2020 AND 17SEP2020,
DEVELOPED MODERATE
BILATERAL ANTERIOR THIGH
PAIN ON 08NOV2020 FOR
WHICH HE TOOK PRN
IBUPROFEN. PAIN SEEMED
DISPROPORTIONAL TO
ACTIVITY SO SUBJECT SAW
PCP 09NOV2020. LABS
REVEALED ELEVATED AST,
ALT AND FURTHER WORK-UP
WAS SCHEDULED, IBUPROFEN
DISCONTINUED. NO OTHER
SYMPTOMS DEVELOPED AND
PAIN DOWN TO 1/10 ON
12NOV2020 BUT CK RETURNED
"VERY HIGH" AND SUBJECT
INSTRUCTED BY PCP TO GO TO
ER. SUBJECT ADMITTED FOR
FLUIDS; AST, ALT, CK HAVE
BEEN COMING DOWN; SUBJECT
REPORTS FEELING "GREAT."
SAE OF RHABDOMYOLYSIS,
NOT RELATED TO IP,
PROBABLY PARTIALLY
RELATED TO SUBJECT'S
SOCCER ACTIVITIES, PERHAPS
VIRAL MYOSITIS. WILL
PROCURE MEDICAL RECORDS
FOR DETAILS AND FURTHER
ELUCIDATION. UPDATE:

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 15:50:13

Generated On: 09 Jun 2021 17:00:21

SUBJECT DC FROM HOSPITAL
13NOV2020, LIVER US
NEGATIVE, FLU, HEPATITS AND
MONO VIRUS TESTS
NEGATIVE, OVEREXERTION
DUE TO SOCCER IN SETTING OF
DEHYDRATION RHABDO. HAS
INCREASE WATER INTAKE AND
HAS FOLLOW UP WITH PCP
THIS WEEK. MEDICAL
RECORDS PENDING. UPDATE
13JAN2021: MEDICAL RECORDS
REVIEWED AND CONFIRM
SUBJECT'S REPORT OF
HOSPITALIZATION FOR IV
FLUIDS TREATMENT FOR
RHABDOMYOLYSIS RELATED
TO OVEREXERTION
INVOLVING BILATERAL
QUADRICEPS. SUBJECT
ADMITTED 12NOV20 AND
DISCHARGED 14NOV20. IN
HOSPITAL LABS SHOWED CK
>20K, AST 1137, ALT 306 ON
ADMIT AND 1672, 548, AND 223
BEFORE DISCHARGE,
RESPECTIVELY. LIVER
ULTRASOUND, HEPATITIS
PANEL, KIDNEY FUNCTION
TESTS, ACETAMINOPHEN
LEVELS, AND COVID TEST
WERE UNREMARKABLE OR
NEGATIVE. SUBJECT
INCREASED HYDRATION,
MODERATED EXERCISE, HAS

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 15:50:13

Generated On: 09 Jun 2021 17:00:21

FELT WELL, AND REPORTS
THAT AT F/U WITH PCP ON
02DEC2020 CK, AST AND ALT
WERE 2686, 82, AND 50
RESPECTIVELY AND NO
FURTHER WORK-UP PLAN.SAE
OF RHABDOMYOLYSIS, NR TO
IP, G3, RESOLVED

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

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Apr 2021 20:58:57

Generated On: 09 Jun 2021 17:00:21

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

Yes ☒

No ☐

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

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 20:58:57

Generated On: 09 Jun 2021 17:00:21

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication RHABDOMYLOYSIS

Dose per administration 400

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

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 20:58:57

Generated On: 09 Jun 2021 17:00:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	08 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 09 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 20:58:57

Generated On: 09 Jun 2021 17:00:21

Name of Medication SODIUM CHLORIDE 0.9%

Prophylaxis Yes ☐
No ☒

Indication RHABDOMYOLYSIS

Dose per administration 1000

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

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 20:58:57

Generated On: 09 Jun 2021 17:00:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3312187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 20:58:57

Generated On: 09 Jun 2021 17:00:21

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3312187

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:00:21

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

US3312187

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:00:21

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

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

SAEID	USA-US300-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	LENEXA
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

SAEID	USA-US300-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	LENEXA
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	17/NOV/2020 00:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

SAEID	USA-US300-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	LENEXA
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/NOV/2020 16:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

SAEID	USA-US300-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	LENEXA
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	18/DEC/2020 15:31
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form (4)

Data signed: (b) (4) 05 Apr 2021 20:58:58

Generated On: 09 Jun 2021 17:00:21

SAEID	USA-US300-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	LENEXA
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	14/JAN/2021 09:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3312187 (Prod: Johnson County Clin-Trials)

US3312187

Form: Participant Creation

Generated On: 09 Jun 2021 17:00:21

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'US3312187'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 15:59:37

US3312187

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 17:05:34

US3312187

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 15:59:38

US3312187

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	20 Aug 2020 17:05:34

US3312187

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User entered 'SCRN'	System	20 Aug 2020 17:05:34

US3312187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:21

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered (b) (6) 1989'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 15:59:39

US3312187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:21

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '31'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:58:03

US3312187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:21

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User entered 'YEARS'	System	26 Aug 2020 23:58:03

US3312187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:21

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User entered '31'	System	20 Aug 2020 17:05:47

US3312187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:21

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Male (M)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:58:03

US3312187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:21

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:58:03

US3312187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:21

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:58:03

US3312187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:21

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:58:03

US3312187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:21

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:58:03

US3312187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:21

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:58:03

US3312187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:21

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:58:03

US3312187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:58:03

US3312187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:21

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:58:03

US3312187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:21

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:58:03

US3312187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:21

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:58:03

US3312187

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:21

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '20 Aug 2020'	Christa Estrada (b) (4)	20 Aug 2020 17:05:47

US3312187

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User entered 'Aug 2020'	System	20 Aug 2020 17:05:47

US3312187

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User entered '2020'	System	20 Aug 2020 17:05:47

US3312187

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:21

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Amendment 2 (2)'	Christa Estrada (b) (4)	20 Aug 2020 17:05:47

US3312187

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 17:05:47

US3312187

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered empty.	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 17:05:47

US3312187

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:21

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered empty.	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 17:05:47

US3312187

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:21

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 17:05:47

US3312187

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:21

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 15:59:38

US3312187

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:21

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User entered 'I'	System	20 Aug 2020 17:05:55

US3312187

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	Christa Estrada (b) (4)	20 Aug 2020 17:05:55

US3312187

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:00:21

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:58:15

US3312187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:58:45

US3312187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '20 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:58:45

US3312187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '11:05'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:58:45

US3312187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User entered '20 Aug 2020 11:05'	System	26 Aug 2020 23:58:45

US3312187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '69' in	(b) (4)	26 Aug 2020 23:58:45
DataPoint set to visible.	Karol Moore (b) (4)	20 Aug 2020 17:05:55
	(b) (4)	
	System	

US3312187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '205' lb	(b) (4) Karol Moore (b) (4)	26 Aug 2020 23:58:45
DataPoint set to visible.	(b) (4) System	20 Aug 2020 17:05:55

US3312187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
Amendment Manager: User entered '30.33651'	System	17 Sep 2020 00:16:09
User entered '30.3'	System	26 Aug 2020 23:58:45
DataPoint set to visible.	System	20 Aug 2020 17:05:55

US3312187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User entered 'kg/m2'	System	26 Aug 2020 23:58:45
DataPoint set to visible.	System	20 Aug 2020 17:05:55

US3312187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:58:45

US3312187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:58:45

US3312187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:58:45

US3312187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:58:45

US3312187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User entered 'bpm'	System	26 Aug 2020 23:58:45

US3312187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:58:45

US3312187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User entered 'breaths/min'	System	26 Aug 2020 23:58:45

US3312187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	26 Aug 2020 23:58:45

US3312187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User entered 'mmHg'	System	26 Aug 2020 23:58:45

US3312187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:58:45

US3312187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User entered 'mmHg'	System	26 Aug 2020 23:58:45

US3312187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55

US3312187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55

US3312187

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:58:57

US3312187

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '20 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:58:57

US3312187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:59:38

US3312187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:59:38

US3312187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:59:38

US3312187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:59:38

US3312187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	26 Aug 2020 23:59:38

US3312187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	26 Aug 2020 23:59:38

US3312187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:59:38

US3312187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:59:38

US3312187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	26 Aug 2020 23:59:38

US3312187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:59:38

US3312187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:59:38

US3312187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:21

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:59:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered empty.	(b) (4) Karol Moore (b) (4)	26 Aug 2020 23:59:38

US3312187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:21

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:59:38

US3312187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:21

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:59:38

US3312187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:59:38

US3312187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '0'	(b) (4) Karol Moore (b) (4)	26 Aug 2020 23:59:38

US3312187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:59:38

US3312187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '0'	(b) (4) Karol Moore (b) (4)	26 Aug 2020 23:59:38

US3312187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:59:38

US3312187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:54:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'resides in community with ongoing person to person transmission'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Aug 2020 23:59:38

US3312187

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 17:06:27

US3312187

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '20 Aug 2020'	(b) (4)	20 Aug 2020 17:06:27
	Christa Estrada (b) (4)	
	(b) (4)	

US3312187

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Clinic (Clinic)'	(b) (4) Christa Estrada (b) (4) (b) (4)	20 Aug 2020 17:06:27

US3312187

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User entered 'VISIT1'	System	20 Aug 2020 17:06:27

US3312187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 16:35:20

US3312187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:53:25
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:53:24
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 16:35:20
User entered '106436' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 16:35:20

US3312187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 16:35:20

US3312187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 17:06:41

US3312187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'No (N)'	Christa Estrada (b) (4)	20 Aug 2020 17:06:41

US3312187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 17:06:41

US3312187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:21

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 17:06:41

US3312187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:21

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 17:06:41

US3312187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	06 Oct 2020 17:49:40
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:36:59
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:45:29

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:21

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '20 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '11:05'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User entered '20 Aug 2020 11:05'	System	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '98.3' F	(b) (4)	27 Aug 2020 00:00:28
	Karol Moore (b) (4)	
	(b) (4)	

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '55'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User entered 'bpm'	System	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '12'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User entered 'breaths/min'	System	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '136'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User entered 'mmHg'	System	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '81'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User entered 'mmHg'	System	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '20 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '12:33'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User entered '20 Aug 2020 12:33'	System	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '98.3' F	(b) (4) Karol Moore (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:28

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '56'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User entered 'bpm'	System	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User entered 'breaths/min'	System	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '130'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User entered 'mmHg'	System	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '84'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User entered 'mmHg'	System	27 Aug 2020 00:00:28

US3312187

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:33

US3312187

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:33

US3312187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 17:07:08

US3312187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered empty.	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 17:07:08

US3312187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered empty.	Christa Estrada (b) (4)	20 Aug 2020 17:07:08

US3312187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 17:07:08

US3312187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '20 Aug 2020'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 17:07:08

US3312187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '12:02'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 17:07:08

US3312187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User entered '20 Aug 2020 12:02'	System	20 Aug 2020 17:07:08

US3312187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4)	20 Aug 2020 17:07:08

US3312187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User entered 'ONCE'	System	20 Aug 2020 17:07:08

US3312187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 17:07:08

US3312187

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:45

US3312187

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '20 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:45

US3312187

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '11:28'	(b) (4)	27 Aug 2020 00:00:45
	Karol Moore (b) (4)	
	(b) (4)	

US3312187

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User entered '20 Aug 2020 11:28'	System	27 Aug 2020 00:00:45

US3312187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:00:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '20 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:56

US3312187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:56

US3312187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:56

US3312187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '11:24'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:56

US3312187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User entered '20 Aug 2020 11:24'	System	27 Aug 2020 00:00:56

US3312187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:56

US3312187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:56

US3312187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:56

US3312187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User entered empty.	System	27 Aug 2020 00:00:56

US3312187

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:00:59

US3312187

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User entered 'I'	System	27 Aug 2020 00:00:59

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T12:36:07', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'de0ae6da-5a9d-4688-b42b-823c0177314e' User entered 'Yes (Y)'	System	20 Aug 2020 17:36:45
	System	20 Aug 2020 17:36:45

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T12:36:16', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'de0ae6da-5a9d-4688-b42b-823c0177314e' User entered '98.3'	System	20 Aug 2020 17:36:45
	System	20 Aug 2020 17:36:45

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T12:36:32', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'de0ae6da-5a9d-4688-b42b-823c0177314e' User entered 'No (N)'	System	20 Aug 2020 17:36:45
	System	20 Aug 2020 17:36:45

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T12:36:42', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'de0ae6da-5a9d-4688-b42b-823c0177314e' User entered '20 Aug 2020 12:36'	System	20 Aug 2020 17:36:45
	System	20 Aug 2020 17:36:45

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '20 Aug 2020 12:22'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '20 Aug 2020 14:52'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T18:02:32', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '16d86df5-7d84-4667-a364-413dd3294661' User entered 'Yes (Y)'	System	20 Aug 2020 23:02:46
	System	20 Aug 2020 23:02:46

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T18:02:36', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '16d86df5-7d84-4667-a364-413dd3294661' User entered '97.3'	System	20 Aug 2020 23:02:46
	System	20 Aug 2020 23:02:46

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T18:02:39', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '16d86df5-7d84-4667-a364-413dd3294661' User entered 'No (N)'	System	20 Aug 2020 23:02:46
	System	20 Aug 2020 23:02:46

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T18:02:42', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '16d86df5-7d84-4667-a364-413dd3294661'	System	20 Aug 2020 23:02:46
User entered '20 Aug 2020 18:02'	System	20 Aug 2020 23:02:46

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '20 Aug 2020 15:47'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 2'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:00:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-21T19:45:33', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '47ba80ba-7158-4d14-93a3-0887ccbad454' User entered 'Yes (Y)'	System	22 Aug 2020 00:45:52
	System	22 Aug 2020 00:45:52

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:00:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-21T19:45:38', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '47ba80ba-7158-4d14-93a3-0887ccbad454' User entered '96.8'	System	22 Aug 2020 00:45:52
	System	22 Aug 2020 00:45:52

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-21T19:45:40', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '47ba80ba-7158-4d14-93a3-0887ccbad454'	System	22 Aug 2020 00:45:52
User entered 'No (N)'	System	22 Aug 2020 00:45:52

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-21T19:45:48', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '47ba80ba-7158-4d14-93a3-0887ccbad454' User entered '21 Aug 2020 19:45'	System	22 Aug 2020 00:45:52
	System	22 Aug 2020 00:45:52

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 3'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-22T16:24:46', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'cb7e4583-bcdc-4ec2-b0d1-0cda6f1cc1fe' User entered 'Yes (Y)'	System	22 Aug 2020 21:24:56
	System	22 Aug 2020 21:24:56

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-22T16:24:48', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'cb7e4583-bcdc-4ec2-b0d1-0cda6f1cc1fe' User entered '98.3'	System	22 Aug 2020 21:24:56
	System	22 Aug 2020 21:24:56

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-22T16:24:51', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'cb7e4583-bcdc-4ec2-b0d1-0cda6f1cc1fe' User entered 'No (N)'	System	22 Aug 2020 21:24:56
	System	22 Aug 2020 21:24:56

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-22T16:24:53', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'cb7e4583-bcdc-4ec2-b0d1-0cda6f1cc1fe' User entered '22 Aug 2020 16:24'	System	22 Aug 2020 21:24:56
	System	22 Aug 2020 21:24:56

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 4'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-23T19:45:36', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5251c16c-07c6-4af7-a93e-bc2355a53b9d' User entered 'Yes (Y)'	System	24 Aug 2020 00:45:47
	System	24 Aug 2020 00:45:47

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-23T19:45:39', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5251c16c-07c6-4af7-a93e-bc2355a53b9d' User entered '97.8'	System	24 Aug 2020 00:45:47
	System	24 Aug 2020 00:45:47

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-23T19:45:41', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5251c16c-07c6-4af7-a93e-bc2355a53b9d' User entered 'No (N)'	System	24 Aug 2020 00:45:47
	System	24 Aug 2020 00:45:47

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-23T19:45:43', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5251c16c-07c6-4af7-a93e-bc2355a53b9d' User entered '23 Aug 2020 19:45'	System	24 Aug 2020 00:45:47
	System	24 Aug 2020 00:45:47

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 5'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:00:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-24T17:08:51', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '46e53f80-9136-4fb5-ba53-69970147f49f' User entered 'Yes (Y)'	System	24 Aug 2020 22:10:15
	System	24 Aug 2020 22:10:15

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:00:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-24T17:10:07', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '46e53f80-9136-4fb5-ba53-69970147f49f' User entered '97.5'	System	24 Aug 2020 22:10:15
	System	24 Aug 2020 22:10:15

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-24T17:10:08', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '46e53f80-9136-4fb5-ba53-69970147f49f' User entered 'No (N)'	System	24 Aug 2020 22:10:15
	System	24 Aug 2020 22:10:15

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-24T17:10:12', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '46e53f80-9136-4fb5-ba53-69970147f49f' User entered '24 Aug 2020 17:10'	System	24 Aug 2020 22:10:15
	System	24 Aug 2020 22:10:15

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 6'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:00:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-25T17:33:19', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'b7e9a255-5525-4e2a-b2d1-7678e1c21718'	System	25 Aug 2020 22:33:40
User entered 'Yes (Y)'	System	25 Aug 2020 22:33:40

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:00:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-25T17:33:22', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'b7e9a255-5525-4e2a-b2d1-7678e1c21718' User entered '97.1'	System	25 Aug 2020 22:33:40
	System	25 Aug 2020 22:33:40

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-25T17:33:23', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'b7e9a255-5525-4e2a-b2d1-7678e1c21718'	System	25 Aug 2020 22:33:40
User entered 'No (N)'	System	25 Aug 2020 22:33:40

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-25T17:33:25', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'b7e9a255-5525-4e2a-b2d1-7678e1c21718'	System	25 Aug 2020 22:33:40
User entered '25 Aug 2020 17:33'	System	25 Aug 2020 22:33:40

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 7'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:00:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-26T14:49:45', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '683abed0-8552-4837-8317-042480d9c513' User entered 'Yes (Y)'	System	26 Aug 2020 19:50:04
	System	26 Aug 2020 19:50:04

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:00:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-26T14:49:54', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '683abed0-8552-4837-8317-042480d9c513' User entered '97.9'	System	26 Aug 2020 19:50:04
	System	26 Aug 2020 19:50:04

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-26T14:49:56', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '683abed0-8552-4837-8317-042480d9c513'	System	26 Aug 2020 19:50:04
User entered 'No (N)'	System	26 Aug 2020 19:50:04

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-26T14:49:58', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '683abed0-8552-4837-8317-042480d9c513' User entered '26 Aug 2020 14:49'	System	26 Aug 2020 19:50:04
	System	26 Aug 2020 19:50:04

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T12:37:04', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '18917a74-75d9-4d7c-8046-562b59260d0d'	System	20 Aug 2020 17:37:26
User entered 'None (1)'	System	20 Aug 2020 17:37:26

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T12:37:09', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '18917a74-75d9-4d7c-8046-562b59260d0d'	System	20 Aug 2020 17:37:26
User entered 'No (N)'	System	20 Aug 2020 17:37:26

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T12:37:12', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '18917a74-75d9-4d7c-8046-562b59260d0d'	System	20 Aug 2020 17:37:26
User entered 'No (N)'	System	20 Aug 2020 17:37:26

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T12:37:18', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '18917a74-75d9-4d7c-8046-562b59260d0d'	System	20 Aug 2020 17:37:26
User entered 'None (1)'	System	20 Aug 2020 17:37:26

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T12:37:22', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '18917a74-75d9-4d7c-8046-562b59260d0d' User entered '20 Aug 2020 12:37'	System	20 Aug 2020 17:37:26
	System	20 Aug 2020 17:37:26

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '20 Aug 2020 12:22'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '20 Aug 2020 14:52'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T18:02:47', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '9509db98-70fa-4da2-9ac4-198df6c155ef' User entered 'None (1)'	System	20 Aug 2020 23:03:04
	System	20 Aug 2020 23:03:04

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T18:02:50', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '9509db98-70fa-4da2-9ac4-198df6c155ef' User entered 'No (N)'	System	20 Aug 2020 23:03:04
	System	20 Aug 2020 23:03:04

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T18:02:54', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '9509db98-70fa-4da2-9ac4-198df6c155ef' User entered 'No (N)'	System	20 Aug 2020 23:03:04
	System	20 Aug 2020 23:03:04

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T18:02:58', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '9509db98-70fa-4da2-9ac4-198df6c155ef'	System	20 Aug 2020 23:03:04
User entered 'None (1)'	System	20 Aug 2020 23:03:04

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T18:03:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '9509db98-70fa-4da2-9ac4-198df6c155ef' User entered '20 Aug 2020 18:03'	System	20 Aug 2020 23:03:04
	System	20 Aug 2020 23:03:04

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '20 Aug 2020 15:47'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 2'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-21T19:45:52', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '4300a7b8-a681-4711-85b2-9002b9a9bc44'	System	22 Aug 2020 00:46:08
User entered 'None (1)'	System	22 Aug 2020 00:46:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:00:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-21T19:45:57', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '4300a7b8-a681-4711-85b2-9002b9a9bc44'	System	22 Aug 2020 00:46:08
User entered 'No (N)'	System	22 Aug 2020 00:46:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-21T19:46:03', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '4300a7b8-a681-4711-85b2-9002b9a9bc44'	System	22 Aug 2020 00:46:08
User entered 'No (N)'	System	22 Aug 2020 00:46:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-21T19:46:05', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '4300a7b8-a681-4711-85b2-9002b9a9bc44'	System	22 Aug 2020 00:46:08
User entered 'None (1)'	System	22 Aug 2020 00:46:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-21T19:46:07', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '4300a7b8-a681-4711-85b2-9002b9a9bc44'	System	22 Aug 2020 00:46:08
User entered '21 Aug 2020 19:46'	System	22 Aug 2020 00:46:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 3'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-22T16:24:56', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '9791d69e-4870-49a6-b910-75ed2a611d65'	System	22 Aug 2020 21:25:06
User entered 'None (1)'	System	22 Aug 2020 21:25:06

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-22T16:24:57', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '9791d69e-4870-49a6-b910-75ed2a611d65'	System	22 Aug 2020 21:25:06
User entered 'No (N)'	System	22 Aug 2020 21:25:06

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-22T16:24:59', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '9791d69e-4870-49a6-b910-75ed2a611d65'	System	22 Aug 2020 21:25:06
User entered 'No (N)'	System	22 Aug 2020 21:25:06

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-22T16:25:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '9791d69e-4870-49a6-b910-75ed2a611d65'	System	22 Aug 2020 21:25:06
User entered 'None (1)'	System	22 Aug 2020 21:25:06

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-22T16:25:02', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '9791d69e-4870-49a6-b910-75ed2a611d65'	System	22 Aug 2020 21:25:06
User entered '22 Aug 2020 16:25'	System	22 Aug 2020 21:25:06

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 4'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-23T19:45:45', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'eee1fad1-6c93-48b4-9755-e84ccaf1a3ce' User entered 'None (1)'	System	24 Aug 2020 00:45:57
	System	24 Aug 2020 00:45:57

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-23T19:45:47', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'eee1fad1-6c93-48b4-9755-e84ccaf1a3ce' User entered 'No (N)'	System	24 Aug 2020 00:45:57
	System	24 Aug 2020 00:45:57

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-23T19:45:49', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'eee1fad1-6c93-48b4-9755-e84ccaf1a3ce' User entered 'No (N)'	System	24 Aug 2020 00:45:57
	System	24 Aug 2020 00:45:57

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-23T19:45:51', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'eee1fad1-6c93-48b4-9755-e84ccaf1a3ce' User entered 'None (1)'	System	24 Aug 2020 00:45:57
	System	24 Aug 2020 00:45:57

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-23T19:45:52', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'eee1fad1-6c93-48b4-9755-e84ccaf1a3ce' User entered '23 Aug 2020 19:45'	System	24 Aug 2020 00:45:57
	System	24 Aug 2020 00:45:57

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 5'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-24T17:10:20', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '16c64873-427e-4aee-b211-d2d3dbb9ee08' User entered 'None (1)'	System	24 Aug 2020 22:10:27
	System	24 Aug 2020 22:10:27

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-24T17:10:22', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '16c64873-427e-4aee-b211-d2d3dbb9ee08'	System	24 Aug 2020 22:10:27
User entered 'No (N)'	System	24 Aug 2020 22:10:27

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-24T17:10:23', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '16c64873-427e-4aee-b211-d2d3dbb9ee08' User entered 'No (N)'	System	24 Aug 2020 22:10:27
	System	24 Aug 2020 22:10:27

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-24T17:10:24', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '16c64873-427e-4aee-b211-d2d3dbb9ee08' User entered 'None (1)'	System	24 Aug 2020 22:10:27

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-24T17:10:26', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '16c64873-427e-4aee-b211-d2d3dbb9ee08' User entered '24 Aug 2020 17:10'	System	24 Aug 2020 22:10:27
	System	24 Aug 2020 22:10:27

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 6'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-25T17:33:27', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5b064f19-04ce-4802-9b27-53d31f9fa68c' User entered 'None (1)'	System	25 Aug 2020 22:33:43
	System	25 Aug 2020 22:33:43

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-25T17:33:29', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5b064f19-04ce-4802-9b27-53d31f9fa68c' User entered 'No (N)'	System	25 Aug 2020 22:33:43
	System	25 Aug 2020 22:33:43

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-25T17:33:31', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5b064f19-04ce-4802-9b27-53d31f9fa68c' User entered 'No (N)'	System	25 Aug 2020 22:33:43
	System	25 Aug 2020 22:33:43

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-25T17:33:32', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5b064f19-04ce-4802-9b27-53d31f9fa68c' User entered 'None (1)'	System	25 Aug 2020 22:33:43
	System	25 Aug 2020 22:33:43

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-25T17:33:34', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5b064f19-04ce-4802-9b27-53d31f9fa68c' User entered '25 Aug 2020 17:33'	System	25 Aug 2020 22:33:43
	System	25 Aug 2020 22:33:43

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 7'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-26T14:50:02', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '934cbb95-9d8f-4fd5-b07e-503b25919854'	System	26 Aug 2020 19:50:11
User entered 'None (1)'	System	26 Aug 2020 19:50:11

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-26T14:50:04', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '934cbb95-9d8f-4fd5-b07e-503b25919854'	System	26 Aug 2020 19:50:11
User entered 'No (N)'	System	26 Aug 2020 19:50:11

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-26T14:50:05', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '934cbb95-9d8f-4fd5-b07e-503b25919854' User entered 'No (N)'	System	26 Aug 2020 19:50:11
	System	26 Aug 2020 19:50:11

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-26T14:50:06', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '934cbb95-9d8f-4fd5-b07e-503b25919854'	System	26 Aug 2020 19:50:11
User entered 'None (1)'	System	26 Aug 2020 19:50:11

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-26T14:50:08', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '934cbb95-9d8f-4fd5-b07e-503b25919854'	System	26 Aug 2020 19:50:11
User entered '26 Aug 2020 14:50'	System	26 Aug 2020 19:50:11

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T12:37:31', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '0112ac1e-80c9-4d1f-83fc-3e60ffbd26e7' User entered 'None (0)'	System	20 Aug 2020 17:37:54
	System	20 Aug 2020 17:37:54

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T12:37:33', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '0112ac1e-80c9-4d1f-83fc-3e60ffbd26e7' User entered 'None (0)'	System	20 Aug 2020 17:37:54
	System	20 Aug 2020 17:37:54

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T12:37:37', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '0112ac1e-80c9-4d1f-83fc-3e60ffbd26e7' User entered 'None (0)'	System	20 Aug 2020 17:37:54
	System	20 Aug 2020 17:37:54

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T12:37:39', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '0112ac1e-80c9-4d1f-83fc-3e60ffbd26e7' User entered 'None (0)'	System	20 Aug 2020 17:37:54
	System	20 Aug 2020 17:37:54

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T12:37:43', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '0112ac1e-80c9-4d1f-83fc-3e60ffbd26e7' User entered 'None (0)'	System	20 Aug 2020 17:37:54
	System	20 Aug 2020 17:37:54

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T12:37:45', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '0112ac1e-80c9-4d1f-83fc-3e60ffbd26e7' User entered 'None (0)'	System	20 Aug 2020 17:37:54
	System	20 Aug 2020 17:37:54

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T12:37:50', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '0112ac1e-80c9-4d1f-83fc-3e60ffbd26e7'	System	20 Aug 2020 17:37:54
User entered 'No (N)'	System	20 Aug 2020 17:37:54

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T12:37:53', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '0112ac1e-80c9-4d1f-83fc-3e60ffbd26e7' User entered '20 Aug 2020 12:37'	System	20 Aug 2020 17:37:54
	System	20 Aug 2020 17:37:54

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '20 Aug 2020 12:22'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '20 Aug 2020 14:52'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T18:03:05', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5514a27d-6201-407b-b73e-e9fd3bf55cc0' User entered 'None (0)'	System	20 Aug 2020 23:03:24
	System	20 Aug 2020 23:03:24

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T18:03:06', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5514a27d-6201-407b-b73e-e9fd3bf55cc0' User entered 'None (0)'	System	20 Aug 2020 23:03:24
	System	20 Aug 2020 23:03:24

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T18:03:08', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5514a27d-6201-407b-b73e-e9fd3bf55cc0' User entered 'None (0)'	System	20 Aug 2020 23:03:24
	System	20 Aug 2020 23:03:24

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T18:03:10', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5514a27d-6201-407b-b73e-e9fd3bf55cc0' User entered 'None (0)'	System	20 Aug 2020 23:03:24
	System	20 Aug 2020 23:03:24

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T18:03:12', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5514a27d-6201-407b-b73e-e9fd3bf55cc0' User entered 'None (0)'	System	20 Aug 2020 23:03:24
	System	20 Aug 2020 23:03:24

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T18:03:14', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5514a27d-6201-407b-b73e-e9fd3bf55cc0' User entered 'None (0)'	System	20 Aug 2020 23:03:24
	System	20 Aug 2020 23:03:24

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T18:03:19', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5514a27d-6201-407b-b73e-e9fd3bf55cc0' User entered 'No (N)'	System	20 Aug 2020 23:03:24
	System	20 Aug 2020 23:03:24

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-20T18:03:21', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5514a27d-6201-407b-b73e-e9fd3bf55cc0' User entered '20 Aug 2020 18:03'	System	20 Aug 2020 23:03:24
	System	20 Aug 2020 23:03:24

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '20 Aug 2020 15:47'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 2'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-21T19:46:09', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '2af15397-4091-4071-b86c-c81ee0085a00'	System	22 Aug 2020 00:46:21
User entered 'None (0)'	System	22 Aug 2020 00:46:21

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-21T19:46:10', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '2af15397-4091-4071-b86c-c81ee0085a00'	System	22 Aug 2020 00:46:21
User entered 'None (0)'	System	22 Aug 2020 00:46:21

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-21T19:46:11', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '2af15397-4091-4071-b86c-c81ee0085a00' User entered 'None (0)'	System	22 Aug 2020 00:46:21
	System	22 Aug 2020 00:46:21

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-21T19:46:12', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '2af15397-4091-4071-b86c-c81ee0085a00' User entered 'None (0)'	System	22 Aug 2020 00:46:21
	System	22 Aug 2020 00:46:21

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-21T19:46:13', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '2af15397-4091-4071-b86c-c81ee0085a00' User entered 'None (0)'	System	22 Aug 2020 00:46:21
	System	22 Aug 2020 00:46:21

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-21T19:46:14', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '2af15397-4091-4071-b86c-c81ee0085a00' User entered 'None (0)'	System	22 Aug 2020 00:46:21
	System	22 Aug 2020 00:46:21

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-21T19:46:16', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '2af15397-4091-4071-b86c-c81ee0085a00' User entered 'No (N)'	System	22 Aug 2020 00:46:21
	System	22 Aug 2020 00:46:21

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-21T19:46:18', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '2af15397-4091-4071-b86c-c81ee0085a00' User entered '21 Aug 2020 19:46'	System	22 Aug 2020 00:46:21
	System	22 Aug 2020 00:46:21

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 3'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-22T16:25:07', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '762e4d2f-b9cb-4277-a662-b4b9210edc37' User entered 'None (0)'	System	22 Aug 2020 21:25:20
	System	22 Aug 2020 21:25:20

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-22T16:25:08', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '762e4d2f-b9cb-4277-a662-b4b9210edc37' User entered 'None (0)'	System	22 Aug 2020 21:25:20
	System	22 Aug 2020 21:25:20

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-22T16:25:09', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '762e4d2f-b9cb-4277-a662-b4b9210edc37' User entered 'None (0)'	System	22 Aug 2020 21:25:20
	System	22 Aug 2020 21:25:20

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-22T16:25:10', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '762e4d2f-b9cb-4277-a662-b4b9210edc37' User entered 'None (0)'	System	22 Aug 2020 21:25:20
	System	22 Aug 2020 21:25:20

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-22T16:25:11', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '762e4d2f-b9cb-4277-a662-b4b9210edc37' User entered 'None (0)'	System	22 Aug 2020 21:25:20
	System	22 Aug 2020 21:25:20

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-22T16:25:12', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '762e4d2f-b9cb-4277-a662-b4b9210edc37' User entered 'None (0)'	System	22 Aug 2020 21:25:20
	System	22 Aug 2020 21:25:20

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-22T16:25:14', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '762e4d2f-b9cb-4277-a662-b4b9210edc37'	System	22 Aug 2020 21:25:20
User entered 'No (N)'	System	22 Aug 2020 21:25:20

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-22T16:25:16', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '762e4d2f-b9cb-4277-a662-b4b9210edc37'	System	22 Aug 2020 21:25:20
User entered '22 Aug 2020 16:25'	System	22 Aug 2020 21:25:20

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 4'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-23T19:45:54', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '8c684829-d334-457f-94b0-87a887c0069d' User entered 'None (0)'	System	24 Aug 2020 00:46:07
	System	24 Aug 2020 00:46:07

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-23T19:45:56', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '8c684829-d334-457f-94b0-87a887c0069d' User entered 'None (0)'	System	24 Aug 2020 00:46:07
	System	24 Aug 2020 00:46:07

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-23T19:45:57', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '8c684829-d334-457f-94b0-87a887c0069d' User entered 'None (0)'	System	24 Aug 2020 00:46:07
	System	24 Aug 2020 00:46:07

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-23T19:45:58', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '8c684829-d334-457f-94b0-87a887c0069d' User entered 'None (0)'	System	24 Aug 2020 00:46:07
	System	24 Aug 2020 00:46:07

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-23T19:45:59', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '8c684829-d334-457f-94b0-87a887c0069d' User entered 'None (0)'	System	24 Aug 2020 00:46:07
	System	24 Aug 2020 00:46:07

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-23T19:46:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '8c684829-d334-457f-94b0-87a887c0069d' User entered 'None (0)'	System	24 Aug 2020 00:46:07
	System	24 Aug 2020 00:46:07

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-23T19:46:02', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '8c684829-d334-457f-94b0-87a887c0069d' User entered 'No (N)'	System	24 Aug 2020 00:46:07
	System	24 Aug 2020 00:46:07

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-23T19:46:04', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '8c684829-d334-457f-94b0-87a887c0069d' User entered '23 Aug 2020 19:46'	System	24 Aug 2020 00:46:07
	System	24 Aug 2020 00:46:07

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 5'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-24T17:10:28', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '3de9b8dc-35d3-4535-ba96-970a775989d3' User entered 'None (0)'	System	24 Aug 2020 22:10:39
	System	24 Aug 2020 22:10:39

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-24T17:10:29', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '3de9b8dc-35d3-4535-ba96-970a775989d3' User entered 'None (0)'	System	24 Aug 2020 22:10:39
	System	24 Aug 2020 22:10:39

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-24T17:10:30', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '3de9b8dc-35d3-4535-ba96-970a775989d3' User entered 'None (0)'	System	24 Aug 2020 22:10:39
	System	24 Aug 2020 22:10:39

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-24T17:10:31', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '3de9b8dc-35d3-4535-ba96-970a775989d3' User entered 'None (0)'	System	24 Aug 2020 22:10:39
	System	24 Aug 2020 22:10:39

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-24T17:10:32', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '3de9b8dc-35d3-4535-ba96-970a775989d3' User entered 'None (0)'	System	24 Aug 2020 22:10:39
	System	24 Aug 2020 22:10:39

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-24T17:10:33', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '3de9b8dc-35d3-4535-ba96-970a775989d3' User entered 'None (0)'	System	24 Aug 2020 22:10:39
	System	24 Aug 2020 22:10:39

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-24T17:10:35', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '3de9b8dc-35d3-4535-ba96-970a775989d3'	System	24 Aug 2020 22:10:39
User entered 'No (N)'	System	24 Aug 2020 22:10:39

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-24T17:10:36', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '3de9b8dc-35d3-4535-ba96-970a775989d3'	System	24 Aug 2020 22:10:39
User entered '24 Aug 2020 17:10'	System	24 Aug 2020 22:10:39

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 6'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-25T17:33:36', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'f57138a2-440a-4e43-a72a-148c583eb70f' User entered 'None (0)'	System	25 Aug 2020 22:33:56
	System	25 Aug 2020 22:33:56

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-25T17:33:37', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'f57138a2-440a-4e43-a72a-148c583eb70f' User entered 'None (0)'	System	25 Aug 2020 22:33:56
	System	25 Aug 2020 22:33:56

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-25T17:33:38', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'f57138a2-440a-4e43-a72a-148c583eb70f' User entered 'None (0)'	System	25 Aug 2020 22:33:56
	System	25 Aug 2020 22:33:56

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-25T17:33:43', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'f57138a2-440a-4e43-a72a-148c583eb70f' User entered 'None (0)'	System	25 Aug 2020 22:33:56
	System	25 Aug 2020 22:33:56

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-25T17:33:44', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'f57138a2-440a-4e43-a72a-148c583eb70f' User entered 'None (0)'	System	25 Aug 2020 22:33:56
	System	25 Aug 2020 22:33:56

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-25T17:33:46', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'f57138a2-440a-4e43-a72a-148c583eb70f' User entered 'None (0)'	System	25 Aug 2020 22:33:56
	System	25 Aug 2020 22:33:56

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-25T17:33:51', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'f57138a2-440a-4e43-a72a-148c583eb70f' User entered 'No (N)'	System	25 Aug 2020 22:33:56
	System	25 Aug 2020 22:33:56

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-25T17:33:55', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'f57138a2-440a-4e43-a72a-148c583eb70f' User entered '25 Aug 2020 17:33'	System	25 Aug 2020 22:33:56
	System	25 Aug 2020 22:33:56

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 7'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-26T14:50:11', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'b8cffeal-0e59-4155-a6db-16a0d20b612d' User entered 'None (0)'	System	26 Aug 2020 19:50:24
	System	26 Aug 2020 19:50:24

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-26T14:50:12', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'b8cffeal-0e59-4155-a6db-16a0d20b612d' User entered 'None (0)'	System	26 Aug 2020 19:50:24
	System	26 Aug 2020 19:50:24

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-26T14:50:13', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'b8cffeal-0e59-4155-a6db-16a0d20b612d' User entered 'None (0)'	System	26 Aug 2020 19:50:24
	System	26 Aug 2020 19:50:24

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-26T14:50:15', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'b8cffeal-0e59-4155-a6db-16a0d20b612d' User entered 'None (0)'	System	26 Aug 2020 19:50:24
	System	26 Aug 2020 19:50:24

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-26T14:50:16', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'b8cffeal-0e59-4155-a6db-16a0d20b612d' User entered 'None (0)'	System	26 Aug 2020 19:50:24
	System	26 Aug 2020 19:50:24

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-26T14:50:17', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'b8cffeal-0e59-4155-a6db-16a0d20b612d' User entered 'None (0)'	System	26 Aug 2020 19:50:24
	System	26 Aug 2020 19:50:24

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-26T14:50:20', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'b8cffeal-0e59-4155-a6db-16a0d20b612d' User entered 'No (N)'	System	26 Aug 2020 19:50:24
	System	26 Aug 2020 19:50:24

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-08-26T14:50:21', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'b8cffeal-0e59-4155-a6db-16a0d20b612d' User entered '26 Aug 2020 14:50'	System	26 Aug 2020 19:50:24
	System	26 Aug 2020 19:50:24

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 17:07:08

US3312187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 17:07:08

US3312187

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:02:37

US3312187

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '27 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:02:37

US3312187

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:02:37

US3312187

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered empty.	(b) (4)	28 Aug 2020 18:02:37
	Karol Moore (b) (4)	
	(b) (4)	

US3312187

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:02:42

US3312187

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User entered 'I'	System	28 Aug 2020 18:02:42

US3312187

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	04 Sep 2020 14:06:16

US3312187

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '3 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	04 Sep 2020 14:06:16

US3312187

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	04 Sep 2020 14:06:16

US3312187

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered empty.	(b) (4)	04 Sep 2020 14:06:16
	Karol Moore (b) (4)	
	(b) (4)	

US3312187

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	04 Sep 2020 14:06:25

US3312187

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:29
User entered 'I'	System	04 Sep 2020 14:06:25

US3312187

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	Christa Estrada (b) (4)	17 Sep 2020 14:01:43

US3312187

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '10 Sep 2020'	Christa Estrada (b) (4)	17 Sep 2020 14:01:43

US3312187

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Contact Made (CONTACT MADE)'	Christa Estrada (b) (4)	17 Sep 2020 14:01:43

US3312187

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered empty.	Christa Estrada (b) (4)	17 Sep 2020 14:01:43

US3312187

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	Christa Estrada (b) (4)	17 Sep 2020 14:01:49

US3312187

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:03
User entered 'I'	System	17 Sep 2020 14:01:49

US3312187

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	Christa Estrada (b) (4)	17 Sep 2020 14:01:59

US3312187

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '17 Sep 2020'	Christa Estrada (b) (4)	17 Sep 2020 14:01:59

US3312187

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

[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 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	17 Sep 2020 14:01:59

US3312187

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered 'VISIT2'	System	17 Sep 2020 14:01:59

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4)	06 Oct 2020 17:28:22
	(b) (4)	

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '17 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '08:09'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered '17 Sep 2020 08:09'	System	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '98.1' F	(b) (4) Karol Moore (b) (4)	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '51'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered 'bpm'	System	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered 'breaths/min'	System	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '126'	(b) (4) Karol Moore (b) (4)	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered 'mmHg'	System	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '83'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered 'mmHg'	System	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '17 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '09:20'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered '17 Sep 2020 09:20'	System	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '98.1' F	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Oct 2020 17:28:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	06 Oct 2020 17:28:30
User entered 'Oral (Oral)' reason for change: Data Entry Error	Karol Moore (b) (4)	06 Oct 2020 17:28:30
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Oct 2020 17:28:22
User entered empty.	Karol Moore (b) (4)	06 Oct 2020 17:28:22
	(b) (4)	

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '49'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered 'bpm'	System	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered 'breaths/min'	System	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '129'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered 'mmHg'	System	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '90'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered 'mmHg'	System	06 Oct 2020 17:28:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:38

US3312187

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '17 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:38

US3312187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	Christa Estrada (b) (4)	17 Sep 2020 14:02:16

US3312187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered empty.	Christa Estrada (b) (4)	17 Sep 2020 14:02:16

US3312187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

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 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered empty.	Christa Estrada (b) (4)	17 Sep 2020 14:02:16

US3312187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 14:02:16

US3312187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '17 Sep 2020'	Christa Estrada (b) (4)	17 Sep 2020 14:02:16

US3312187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '08:50'	Christa Estrada (b) (4)	17 Sep 2020 14:02:16

US3312187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered '17 Sep 2020 08:50'	System	17 Sep 2020 14:02:16

US3312187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4)	17 Sep 2020 14:02:16

US3312187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered 'ONCE'	System	17 Sep 2020 14:02:16

US3312187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 14:02:16

US3312187

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:49

US3312187

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '17 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:49

US3312187

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '08:27'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:49

US3312187

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered '17 Sep 2020 08:27'	System	06 Oct 2020 17:28:49

US3312187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:00:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '17 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:59

US3312187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:59

US3312187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	06 Oct 2020 17:28:59

US3312187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:21

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '08:24'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:59

US3312187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered '17 Sep 2020 08:24'	System	06 Oct 2020 17:28:59

US3312187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:59

US3312187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	06 Oct 2020 17:28:59

US3312187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:21

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:28:59

US3312187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered empty.	System	06 Oct 2020 17:28:59

US3312187

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	Christa Estrada (b) (4)	17 Sep 2020 14:02:22

US3312187

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered 'I'	System	17 Sep 2020 14:02:22

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	17 Sep 2020 14:02:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T09:23:55', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '2c74929a-b9fe-4c23-abe1-c64214ff9611' User entered 'Yes (Y)'	System	17 Sep 2020 14:24:10
	System	17 Sep 2020 14:24:10

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T09:24:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '2c74929a-b9fe-4c23-abe1-c64214ff9611' User entered '98.1'	System	17 Sep 2020 14:24:10
	System	17 Sep 2020 14:24:10

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T09:24:02', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '2c74929a-b9fe-4c23-abe1-c64214ff9611'	System	17 Sep 2020 14:24:10
User entered 'No (N)'	System	17 Sep 2020 14:24:10

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T09:24:07', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '2c74929a-b9fe-4c23-abe1-c64214ff9611' User entered '17 Sep 2020 09:24'	System	17 Sep 2020 14:24:10
	System	17 Sep 2020 14:24:10

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '17 Sep 2020 09:10'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '17 Sep 2020 11:40'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	17 Sep 2020 14:02:16
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T22:39:46', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '2aab90bc-89d4-4b8e-be43-23b632564b5a' User entered 'Yes (Y)'	System	18 Sep 2020 03:39:56
	System	18 Sep 2020 03:39:56

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T22:39:50', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '2aab90bc-89d4-4b8e-be43-23b632564b5a' User entered '97.2'	System	18 Sep 2020 03:39:56
	System	18 Sep 2020 03:39:56

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T22:39:52', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '2aab90bc-89d4-4b8e-be43-23b632564b5a' User entered 'No (N)'	System	18 Sep 2020 03:39:56
	System	18 Sep 2020 03:39:56

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T22:39:54', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '2aab90bc-89d4-4b8e-be43-23b632564b5a' User entered '17 Sep 2020 22:39'	System	18 Sep 2020 03:39:56
	System	18 Sep 2020 03:39:56

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '17 Sep 2020 12:35'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	17 Sep 2020 14:02:16
User entered 'Day 2'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:00:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-18T19:10:20', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '72ebd930-0b48-4bb4-94d6-f7ab8a19e06f' User entered 'Yes (Y)'	System	19 Sep 2020 00:10:34
	System	19 Sep 2020 00:10:34

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:00:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-18T19:10:27', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '72ebd930-0b48-4bb4-94d6-f7ab8a19e06f' User entered '97.6'	System	19 Sep 2020 00:10:34
	System	19 Sep 2020 00:10:34

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-18T19:10:29', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '72ebd930-0b48-4bb4-94d6-f7ab8a19e06f' User entered 'No (N)'	System	19 Sep 2020 00:10:34
	System	19 Sep 2020 00:10:34

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-18T19:10:32', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '72ebd930-0b48-4bb4-94d6-f7ab8a19e06f' User entered '18 Sep 2020 19:10'	System	19 Sep 2020 00:10:34
	System	19 Sep 2020 00:10:34

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	17 Sep 2020 14:02:16
User entered 'Day 3'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-19T22:44:31', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '819daa7e-619e-454f-937d-10db54df7b26' User entered 'Yes (Y)'	System	20 Sep 2020 03:44:42
	System	20 Sep 2020 03:44:42

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-19T22:44:34', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '819daa7e-619e-454f-937d-10db54df7b26' User entered '96.5'	System	20 Sep 2020 03:44:42
	System	20 Sep 2020 03:44:42

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-19T22:44:36', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '819daa7e-619e-454f-937d-10db54df7b26'	System	20 Sep 2020 03:44:42
User entered 'No (N)'	System	20 Sep 2020 03:44:42

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-19T22:44:38', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '819daa7e-619e-454f-937d-10db54df7b26' User entered '19 Sep 2020 22:44'	System	20 Sep 2020 03:44:42
	System	20 Sep 2020 03:44:42

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	17 Sep 2020 14:02:16
User entered 'Day 4'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-20T16:57:09', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '3d413aa9-b923-4a58-8f26-eab4d80f2cd2'	System	20 Sep 2020 21:57:19
User entered 'Yes (Y)'	System	20 Sep 2020 21:57:19

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-20T16:57:14', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '3d413aa9-b923-4a58-8f26-eab4d80f2cd2' User entered '97.9'	System	20 Sep 2020 21:57:19
	System	20 Sep 2020 21:57:19

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-20T16:57:16', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '3d413aa9-b923-4a58-8f26-eab4d80f2cd2'	System	20 Sep 2020 21:57:19
User entered 'No (N)'	System	20 Sep 2020 21:57:19

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-20T16:57:18', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '3d413aa9-b923-4a58-8f26-eab4d80f2cd2'	System	20 Sep 2020 21:57:19
User entered '20 Sep 2020 16:57'	System	20 Sep 2020 21:57:19

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	17 Sep 2020 14:02:16
User entered 'Day 5'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:00:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-21T23:59:25', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '44b5b96c-19ab-4881-9179-7d21c5aee74d' User entered 'Yes (Y)'	System	22 Sep 2020 04:59:33
	System	22 Sep 2020 04:59:33

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:00:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-21T23:59:28', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '44b5b96c-19ab-4881-9179-7d21c5aee74d' User entered '97.9'	System	22 Sep 2020 04:59:33
	System	22 Sep 2020 04:59:33

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-21T23:59:29', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '44b5b96c-19ab-4881-9179-7d21c5aee74d' User entered 'No (N)'	System	22 Sep 2020 04:59:33
	System	22 Sep 2020 04:59:33

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-21T23:59:31', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '44b5b96c-19ab-4881-9179-7d21c5aee74d' User entered '21 Sep 2020 23:59'	System	22 Sep 2020 04:59:33
	System	22 Sep 2020 04:59:33

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	17 Sep 2020 14:02:16
User entered 'Day 6'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:00:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-22T22:20:11', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'c5f242e5-3692-47ca-855f-10e4e56402ef' User entered 'Yes (Y)'	System	23 Sep 2020 03:20:20
	System	23 Sep 2020 03:20:20

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:00:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-22T22:20:14', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'c5f242e5-3692-47ca-855f-10e4e56402ef' User entered '97.8'	System	23 Sep 2020 03:20:20
	System	23 Sep 2020 03:20:20

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-22T22:20:16', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'c5f242e5-3692-47ca-855f-10e4e56402ef' User entered 'No (N)'	System	23 Sep 2020 03:20:20
	System	23 Sep 2020 03:20:20

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-22T22:20:17', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'c5f242e5-3692-47ca-855f-10e4e56402ef' User entered '22 Sep 2020 22:20'	System	23 Sep 2020 03:20:20
	System	23 Sep 2020 03:20:20

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	17 Sep 2020 14:02:16
User entered 'Day 7'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:00:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-23T16:48:31', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '46b76bdd-cd23-4ef6-a7b6-0cdd23d53ae7' User entered 'Yes (Y)'	System	23 Sep 2020 21:48:41
	System	23 Sep 2020 21:48:41

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:00:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-23T16:48:34', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '46b76bdd-cd23-4ef6-a7b6-0cdd23d53ae7' User entered '97.0'	System	23 Sep 2020 21:48:41
	System	23 Sep 2020 21:48:41

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-23T16:48:35', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '46b76bdd-cd23-4ef6-a7b6-0cdd23d53ae7' User entered 'No (N)'	System	23 Sep 2020 21:48:41
	System	23 Sep 2020 21:48:41

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-23T16:48:37', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '46b76bdd-cd23-4ef6-a7b6-0cdd23d53ae7' User entered '23 Sep 2020 16:48'	System	23 Sep 2020 21:48:41
	System	23 Sep 2020 21:48:41

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	17 Sep 2020 14:02:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T09:24:11', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '8f2241e0-944b-43c2-bb6e-1bdbcec12901' User entered 'None (1)'	System	17 Sep 2020 14:24:22
	System	17 Sep 2020 14:24:22

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T09:24:13', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '8f2241e0-944b-43c2-bb6e-1bdbcec12901' User entered 'No (N)'	System	17 Sep 2020 14:24:22
	System	17 Sep 2020 14:24:22

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T09:24:15', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '8f2241e0-944b-43c2-bb6e-1bdbcec12901' User entered 'No (N)'	System	17 Sep 2020 14:24:22
	System	17 Sep 2020 14:24:22

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T09:24:18', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '8f2241e0-944b-43c2-bb6e-1bdbcec12901' User entered 'None (1)'	System	17 Sep 2020 14:24:22
	System	17 Sep 2020 14:24:22

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T09:24:20', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '8f2241e0-944b-43c2-bb6e-1bdbcec12901' User entered '17 Sep 2020 09:24'	System	17 Sep 2020 14:24:22
	System	17 Sep 2020 14:24:22

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '17 Sep 2020 09:10'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '17 Sep 2020 11:40'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	17 Sep 2020 14:02:16
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T22:39:56', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '46495469-b8e7-4447-9078-8b17d89717ed' User entered 'None (1)'	System	18 Sep 2020 03:40:20
	System	18 Sep 2020 03:40:20

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T22:40:13', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '46495469-b8e7-4447-9078-8b17d89717ed' User entered 'No (N)'	System	18 Sep 2020 03:40:20
	System	18 Sep 2020 03:40:20

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T22:40:15', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '46495469-b8e7-4447-9078-8b17d89717ed' User entered 'No (N)'	System	18 Sep 2020 03:40:20
	System	18 Sep 2020 03:40:20

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T22:40:17', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '46495469-b8e7-4447-9078-8b17d89717ed' User entered 'None (1)'	System	18 Sep 2020 03:40:20
	System	18 Sep 2020 03:40:20

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T22:40:18', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '46495469-b8e7-4447-9078-8b17d89717ed' User entered '17 Sep 2020 22:40'	System	18 Sep 2020 03:40:20
	System	18 Sep 2020 03:40:20

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '17 Sep 2020 12:35'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	17 Sep 2020 14:02:16
User entered 'Day 2'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-18T19:10:35', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '02f34c18-7c11-477e-9a28-7152b3402cbc'	System	19 Sep 2020 00:10:48
User entered 'None (1)'	System	19 Sep 2020 00:10:48

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:00:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-18T19:10:36', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '02f34c18-7c11-477e-9a28-7152b3402cbc' User entered 'No (N)'	System	19 Sep 2020 00:10:48
	System	19 Sep 2020 00:10:48

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-18T19:10:41', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '02f34c18-7c11-477e-9a28-7152b3402cbc' User entered 'No (N)'	System	19 Sep 2020 00:10:48
	System	19 Sep 2020 00:10:48

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-18T19:10:43', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '02f34c18-7c11-477e-9a28-7152b3402cbc' User entered 'None (1)'	System	19 Sep 2020 00:10:48
	System	19 Sep 2020 00:10:48

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-18T19:10:45', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '02f34c18-7c11-477e-9a28-7152b3402cbc' User entered '18 Sep 2020 19:10'	System	19 Sep 2020 00:10:48
	System	19 Sep 2020 00:10:48

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	17 Sep 2020 14:02:16
User entered 'Day 3'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-19T22:44:40', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '0b341266-6f1f-4bd7-8852-8f5b5ac23c56'	System	20 Sep 2020 03:44:48
User entered 'None (1)'	System	20 Sep 2020 03:44:48

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-19T22:44:42', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '0b341266-6f1f-4bd7-8852-8f5b5ac23c56' User entered 'No (N)'	System	20 Sep 2020 03:44:48
	System	20 Sep 2020 03:44:48

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-19T22:44:43', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '0b341266-6f1f-4bd7-8852-8f5b5ac23c56'	System	20 Sep 2020 03:44:48
User entered 'No (N)'	System	20 Sep 2020 03:44:48

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-19T22:44:44', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '0b341266-6f1f-4bd7-8852-8f5b5ac23c56'	System	20 Sep 2020 03:44:48
User entered 'None (1)'	System	20 Sep 2020 03:44:48

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-19T22:44:46', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '0b341266-6f1f-4bd7-8852-8f5b5ac23c56' User entered '19 Sep 2020 22:44'	System	20 Sep 2020 03:44:48
	System	20 Sep 2020 03:44:48

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	17 Sep 2020 14:02:16
User entered 'Day 4'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-20T16:57:20', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '63d36c1f-2e41-4e0d-b88d-e3c9aae19cb2'	System	20 Sep 2020 21:59:29
User entered 'None (1)'	System	20 Sep 2020 21:59:29

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-20T16:57:22', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '63d36c1f-2e41-4e0d-b88d-e3c9aae19cb2' User entered 'No (N)'	System	20 Sep 2020 21:59:29
	System	20 Sep 2020 21:59:29

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-20T16:57:23', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '63d36c1f-2e41-4e0d-b88d-e3c9aae19cb2'	System	20 Sep 2020 21:59:29
User entered 'No (N)'	System	20 Sep 2020 21:59:29

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-20T16:57:24', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '63d36c1f-2e41-4e0d-b88d-e3c9aae19cb2'	System	20 Sep 2020 21:59:29
User entered 'None (1)'	System	20 Sep 2020 21:59:29

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-20T16:57:26', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '63d36c1f-2e41-4e0d-b88d-e3c9aae19cb2' User entered '20 Sep 2020 16:57'	System	20 Sep 2020 21:59:29
	System	20 Sep 2020 21:59:29

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	17 Sep 2020 14:02:16
User entered 'Day 5'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-21T23:59:33', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'c58b2157-f653-4297-b06e-c5891f7c584b' User entered 'None (1)'	System	22 Sep 2020 04:59:41
	System	22 Sep 2020 04:59:41

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-21T23:59:34', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'c58b2157-f653-4297-b06e-c5891f7c584b' User entered 'No (N)'	System	22 Sep 2020 04:59:41
	System	22 Sep 2020 04:59:41

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-21T23:59:35', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'c58b2157-f653-4297-b06e-c5891f7c584b' User entered 'No (N)'	System	22 Sep 2020 04:59:41
	System	22 Sep 2020 04:59:41

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-21T23:59:37', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'c58b2157-f653-4297-b06e-c5891f7c584b' User entered 'None (1)'	System	22 Sep 2020 04:59:41
	System	22 Sep 2020 04:59:41

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-21T23:59:38', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'c58b2157-f653-4297-b06e-c5891f7c584b' User entered '21 Sep 2020 23:59'	System	22 Sep 2020 04:59:41
	System	22 Sep 2020 04:59:41

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	17 Sep 2020 14:02:16
User entered 'Day 6'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-22T22:20:23', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'e21e812c-eb47-4aef-ba21-589005bf0df2'	System	23 Sep 2020 03:20:34
User entered 'None (1)'	System	23 Sep 2020 03:20:34

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-22T22:20:25', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'e21e812c-eb47-4aef-ba21-589005bf0df2' User entered 'No (N)'	System	23 Sep 2020 03:20:34
	System	23 Sep 2020 03:20:34

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-22T22:20:26', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'e21e812c-eb47-4aef-ba21-589005bf0df2'	System	23 Sep 2020 03:20:34
User entered 'No (N)'	System	23 Sep 2020 03:20:34

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-22T22:20:27', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'e21e812c-eb47-4aef-ba21-589005bf0df2' User entered 'None (1)'	System	23 Sep 2020 03:20:34
	System	23 Sep 2020 03:20:34

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-22T22:20:29', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'e21e812c-eb47-4aef-ba21-589005bf0df2' User entered '22 Sep 2020 22:20'	System	23 Sep 2020 03:20:34
	System	23 Sep 2020 03:20:34

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	17 Sep 2020 14:02:16
User entered 'Day 7'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-23T16:48:39', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '6fb4a2ed-9e40-40db-b749-e6a6855a9016' User entered 'None (1)'	System	23 Sep 2020 21:48:49
	System	23 Sep 2020 21:48:49

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-23T16:48:40', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '6fb4a2ed-9e40-40db-b749-e6a6855a9016' User entered 'No (N)'	System	23 Sep 2020 21:48:49
	System	23 Sep 2020 21:48:49

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-23T16:48:41', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '6fb4a2ed-9e40-40db-b749-e6a6855a9016' User entered 'No (N)'	System	23 Sep 2020 21:48:49
	System	23 Sep 2020 21:48:49

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-23T16:48:42', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '6fb4a2ed-9e40-40db-b749-e6a6855a9016' User entered 'None (1)'	System	23 Sep 2020 21:48:49
	System	23 Sep 2020 21:48:49

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-23T16:48:44', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '6fb4a2ed-9e40-40db-b749-e6a6855a9016' User entered '23 Sep 2020 16:48'	System	23 Sep 2020 21:48:49
	System	23 Sep 2020 21:48:49

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	17 Sep 2020 14:02:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T09:24:25', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'ce2d115f-3e76-4b23-b884-e580516e6d9c' User entered 'None (0)'	System	17 Sep 2020 14:24:45
	System	17 Sep 2020 14:24:45

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T09:24:27', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'ce2d115f-3e76-4b23-b884-e580516e6d9c' User entered 'None (0)'	System	17 Sep 2020 14:24:45
	System	17 Sep 2020 14:24:45

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T09:24:29', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'ce2d115f-3e76-4b23-b884-e580516e6d9c' User entered 'None (0)'	System	17 Sep 2020 14:24:45
	System	17 Sep 2020 14:24:45

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T09:24:30', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'ce2d115f-3e76-4b23-b884-e580516e6d9c' User entered 'None (0)'	System	17 Sep 2020 14:24:45
	System	17 Sep 2020 14:24:45

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T09:24:32', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'ce2d115f-3e76-4b23-b884-e580516e6d9c' User entered 'None (0)'	System	17 Sep 2020 14:24:45
	System	17 Sep 2020 14:24:45

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T09:24:33', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'ce2d115f-3e76-4b23-b884-e580516e6d9c' User entered 'None (0)'	System	17 Sep 2020 14:24:45
	System	17 Sep 2020 14:24:45

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T09:24:36', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'ce2d115f-3e76-4b23-b884-e580516e6d9c' User entered 'No (N)'	System	17 Sep 2020 14:24:45
	System	17 Sep 2020 14:24:45

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T09:24:39', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'ce2d115f-3e76-4b23-b884-e580516e6d9c' User entered '17 Sep 2020 09:24'	System	17 Sep 2020 14:24:45
	System	17 Sep 2020 14:24:45

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '17 Sep 2020 09:10'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '17 Sep 2020 11:40'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	17 Sep 2020 14:02:16
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T22:40:21', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '1fc743c8-5009-470c-8290-0e594e715c72'	System	18 Sep 2020 03:40:34
User entered 'None (0)'	System	18 Sep 2020 03:40:34

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T22:40:22', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '1fc743c8-5009-470c-8290-0e594e715c72' User entered 'None (0)'	System	18 Sep 2020 03:40:34
	System	18 Sep 2020 03:40:34

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T22:40:23', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '1fc743c8-5009-470c-8290-0e594e715c72' User entered 'None (0)'	System	18 Sep 2020 03:40:34
	System	18 Sep 2020 03:40:34

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T22:40:24', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '1fc743c8-5009-470c-8290-0e594e715c72' User entered 'None (0)'	System	18 Sep 2020 03:40:34
	System	18 Sep 2020 03:40:34

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T22:40:26', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '1fc743c8-5009-470c-8290-0e594e715c72' User entered 'None (0)'	System	18 Sep 2020 03:40:34
	System	18 Sep 2020 03:40:34

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T22:40:27', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '1fc743c8-5009-470c-8290-0e594e715c72' User entered 'None (0)'	System	18 Sep 2020 03:40:34
	System	18 Sep 2020 03:40:34

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T22:40:29', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '1fc743c8-5009-470c-8290-0e594e715c72'	System	18 Sep 2020 03:40:34
User entered 'No (N)'	System	18 Sep 2020 03:40:34

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-17T22:40:31', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '1fc743c8-5009-470c-8290-0e594e715c72'	System	18 Sep 2020 03:40:34
User entered '17 Sep 2020 22:40'	System	18 Sep 2020 03:40:34

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '17 Sep 2020 12:35'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	17 Sep 2020 14:02:16
User entered 'Day 2'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-18T19:10:47', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'd3b220db-ed1e-4e3d-b5b6-fa5261666cd6' User entered 'None (0)'	System	19 Sep 2020 00:10:59
	System	19 Sep 2020 00:10:59

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-18T19:10:48', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'd3b220db-ed1e-4e3d-b5b6-fa5261666cd6' User entered 'None (0)'	System	19 Sep 2020 00:10:59
	System	19 Sep 2020 00:10:59

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-18T19:10:49', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'd3b220db-ed1e-4e3d-b5b6-fa5261666cd6' User entered 'None (0)'	System	19 Sep 2020 00:10:59
	System	19 Sep 2020 00:10:59

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-18T19:10:51', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'd3b220db-ed1e-4e3d-b5b6-fa5261666cd6' User entered 'None (0)'	System	19 Sep 2020 00:10:59
	System	19 Sep 2020 00:10:59

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-18T19:10:52', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'd3b220db-ed1e-4e3d-b5b6-fa5261666cd6' User entered 'None (0)'	System	19 Sep 2020 00:10:59
	System	19 Sep 2020 00:10:59

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-18T19:10:53', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'd3b220db-ed1e-4e3d-b5b6-fa5261666cd6' User entered 'None (0)'	System	19 Sep 2020 00:10:59
	System	19 Sep 2020 00:10:59

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-18T19:10:55', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'd3b220db-ed1e-4e3d-b5b6-fa5261666cd6' User entered 'No (N)'	System	19 Sep 2020 00:10:59
	System	19 Sep 2020 00:10:59

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-18T19:10:57', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'd3b220db-ed1e-4e3d-b5b6-fa5261666cd6' User entered '18 Sep 2020 19:10'	System	19 Sep 2020 00:10:59
	System	19 Sep 2020 00:10:59

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	17 Sep 2020 14:02:16
User entered 'Day 3'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-19T22:44:48', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '035e6daa-cb40-4cf0-84eb-e7247dc1c31a' User entered 'None (0)'	System	20 Sep 2020 03:45:51
	System	20 Sep 2020 03:45:51

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-19T22:44:49', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '035e6daa-cb40-4cf0-84eb-e7247dc1c31a' User entered 'None (0)'	System	20 Sep 2020 03:45:51
	System	20 Sep 2020 03:45:51

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-19T22:44:50', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '035e6daa-cb40-4cf0-84eb-e7247dc1c31a' User entered 'None (0)'	System	20 Sep 2020 03:45:51
	System	20 Sep 2020 03:45:51

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-19T22:44:51', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '035e6daa-cb40-4cf0-84eb-e7247dc1c31a' User entered 'None (0)'	System	20 Sep 2020 03:45:51
	System	20 Sep 2020 03:45:51

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-19T22:44:52', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '035e6daa-cb40-4cf0-84eb-e7247dc1c31a' User entered 'None (0)'	System	20 Sep 2020 03:45:51
	System	20 Sep 2020 03:45:51

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-19T22:44:53', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '035e6daa-cb40-4cf0-84eb-e7247dc1c31a' User entered 'None (0)'	System	20 Sep 2020 03:45:51
	System	20 Sep 2020 03:45:51

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-19T22:45:02', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '035e6daa-cb40-4cf0-84eb-e7247dc1c31a' User entered 'No (N)'	System	20 Sep 2020 03:45:51
	System	20 Sep 2020 03:45:51

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-19T22:45:03', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '035e6daa-cb40-4cf0-84eb-e7247dc1c31a' User entered '19 Sep 2020 22:45'	System	20 Sep 2020 03:45:51
	System	20 Sep 2020 03:45:51

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	17 Sep 2020 14:02:16
User entered 'Day 4'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-20T16:57:29', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5bd62ccc-401d-4dd6-9ce2-01ebc7665853' User entered 'None (0)'	System	20 Sep 2020 21:59:32
	System	20 Sep 2020 21:59:32

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-20T16:57:30', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5bd62ccc-401d-4dd6-9ce2-01ebc7665853' User entered 'None (0)'	System	20 Sep 2020 21:59:32
	System	20 Sep 2020 21:59:32

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-20T16:57:31', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5bd62ccc-401d-4dd6-9ce2-01ebc7665853' User entered 'None (0)'	System	20 Sep 2020 21:59:32
	System	20 Sep 2020 21:59:32

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-20T16:57:32', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5bd62ccc-401d-4dd6-9ce2-01ebc7665853' User entered 'None (0)'	System	20 Sep 2020 21:59:32
	System	20 Sep 2020 21:59:32

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-20T16:57:33', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5bd62ccc-401d-4dd6-9ce2-01ebc7665853' User entered 'None (0)'	System	20 Sep 2020 21:59:32
	System	20 Sep 2020 21:59:32

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-20T16:57:35', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5bd62ccc-401d-4dd6-9ce2-01ebc7665853' User entered 'None (0)'	System	20 Sep 2020 21:59:32
	System	20 Sep 2020 21:59:32

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-20T16:57:36', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5bd62ccc-401d-4dd6-9ce2-01ebc7665853' User entered 'No (N)'	System	20 Sep 2020 21:59:32
	System	20 Sep 2020 21:59:32

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-20T16:57:38', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5bd62ccc-401d-4dd6-9ce2-01ebc7665853' User entered '20 Sep 2020 16:57'	System	20 Sep 2020 21:59:32
	System	20 Sep 2020 21:59:32

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	17 Sep 2020 14:02:16
User entered 'Day 5'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-21T23:59:40', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '54421521-1d2b-40de-85e0-acfe6811aeb9' User entered 'None (0)'	System	22 Sep 2020 04:59:52
	System	22 Sep 2020 04:59:52

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-21T23:59:41', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '54421521-1d2b-40de-85e0-acfe6811aeb9' User entered 'None (0)'	System	22 Sep 2020 04:59:52
	System	22 Sep 2020 04:59:52

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-21T23:59:42', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '54421521-1d2b-40de-85e0-acfe6811aeb9' User entered 'None (0)'	System	22 Sep 2020 04:59:52
	System	22 Sep 2020 04:59:52

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-21T23:59:43', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '54421521-1d2b-40de-85e0-acfe6811aeb9' User entered 'None (0)'	System	22 Sep 2020 04:59:52
	System	22 Sep 2020 04:59:52

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-21T23:59:44', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '54421521-1d2b-40de-85e0-acfe6811aeb9' User entered 'None (0)'	System	22 Sep 2020 04:59:52
	System	22 Sep 2020 04:59:52

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-21T23:59:45', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '54421521-1d2b-40de-85e0-acfe6811aeb9' User entered 'None (0)'	System	22 Sep 2020 04:59:52
	System	22 Sep 2020 04:59:52

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-21T23:59:46', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '54421521-1d2b-40de-85e0-acfe6811aeb9' User entered 'No (N)'	System	22 Sep 2020 04:59:52
	System	22 Sep 2020 04:59:52

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-21T23:59:48', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '54421521-1d2b-40de-85e0-acfe6811aeb9' User entered '21 Sep 2020 23:59'	System	22 Sep 2020 04:59:52
	System	22 Sep 2020 04:59:52

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	17 Sep 2020 14:02:16
User entered 'Day 6'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-22T22:20:31', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'f25df29a-fb9d-4c9c-af0f-60d85446e12e' User entered 'None (0)'	System	23 Sep 2020 03:20:41
	System	23 Sep 2020 03:20:41

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-22T22:20:32', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'f25df29a-fb9d-4c9c-af0f-60d85446e12e' User entered 'None (0)'	System	23 Sep 2020 03:20:41
	System	23 Sep 2020 03:20:41

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-22T22:20:33', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'f25df29a-fb9d-4c9c-af0f-60d85446e12e' User entered 'None (0)'	System	23 Sep 2020 03:20:41
	System	23 Sep 2020 03:20:41

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-22T22:20:34', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'f25df29a-fb9d-4c9c-af0f-60d85446e12e' User entered 'None (0)'	System	23 Sep 2020 03:20:41
	System	23 Sep 2020 03:20:41

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-22T22:20:35', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'f25df29a-fb9d-4c9c-af0f-60d85446e12e' User entered 'None (0)'	System	23 Sep 2020 03:20:41
	System	23 Sep 2020 03:20:41

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-22T22:20:36', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'f25df29a-fb9d-4c9c-af0f-60d85446e12e' User entered 'None (0)'	System	23 Sep 2020 03:20:41
	System	23 Sep 2020 03:20:41

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-22T22:20:37', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'f25df29a-fb9d-4c9c-af0f-60d85446e12e' User entered 'No (N)'	System	23 Sep 2020 03:20:41
	System	23 Sep 2020 03:20:41

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-22T22:20:38', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'f25df29a-fb9d-4c9c-af0f-60d85446e12e' User entered '22 Sep 2020 22:20'	System	23 Sep 2020 03:20:41
	System	23 Sep 2020 03:20:41

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	17 Sep 2020 14:02:16
User entered 'Day 7'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-23T16:48:46', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '06b85826-0219-42ba-af03-06a04375b452' User entered 'None (0)'	System	23 Sep 2020 21:48:56
	System	23 Sep 2020 21:48:56

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-23T16:48:47', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '06b85826-0219-42ba-af03-06a04375b452' User entered 'None (0)'	System	23 Sep 2020 21:48:56
	System	23 Sep 2020 21:48:56

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-23T16:48:48', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '06b85826-0219-42ba-af03-06a04375b452' User entered 'None (0)'	System	23 Sep 2020 21:48:56
	System	23 Sep 2020 21:48:56

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-23T16:48:48', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '06b85826-0219-42ba-af03-06a04375b452' User entered 'None (0)'	System	23 Sep 2020 21:48:56
	System	23 Sep 2020 21:48:56

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-23T16:48:49', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '06b85826-0219-42ba-af03-06a04375b452' User entered 'None (0)'	System	23 Sep 2020 21:48:56
	System	23 Sep 2020 21:48:56

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-23T16:48:50', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '06b85826-0219-42ba-af03-06a04375b452' User entered 'None (0)'	System	23 Sep 2020 21:48:56
	System	23 Sep 2020 21:48:56

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-23T16:48:51', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '06b85826-0219-42ba-af03-06a04375b452' User entered 'No (N)'	System	23 Sep 2020 21:48:56
	System	23 Sep 2020 21:48:56

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-09-23T16:48:52', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '06b85826-0219-42ba-af03-06a04375b452'	System	23 Sep 2020 21:48:56
User entered '23 Sep 2020 16:48'	System	23 Sep 2020 21:48:56

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 14:02:16

US3312187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:00:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 14:02:16

US3312187

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:29:34

US3312187

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '24 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:29:34

US3312187

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:29:34

US3312187

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:29:34

US3312187

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:29:37

US3312187

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered 'I'	System	06 Oct 2020 17:29:37

US3312187

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:30:22

US3312187

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '01 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:30:22

US3312187

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:30:22

US3312187

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:30:22

US3312187

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:30:30

US3312187

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered 'I'	System	06 Oct 2020 17:30:30

US3312187

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 13:17:58

US3312187

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 13:17:58

US3312187

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 13:17:58

US3312187

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 13:17:58

US3312187

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 13:17:32

US3312187

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered 'I'	System	09 Oct 2020 13:17:32

US3312187

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:42:02

US3312187

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:42:02

US3312187

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

[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 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:42:02

US3312187

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered 'VISIT3'	System	16 Oct 2020 20:42:02

US3312187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:42:37

US3312187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:42:37

US3312187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '08:10'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:42:37

US3312187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered '15 Oct 2020 08:10'	System	16 Oct 2020 20:42:37

US3312187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:42:37

US3312187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:42:37

US3312187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:42:37

US3312187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '62'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:42:37

US3312187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered 'bpm'	System	16 Oct 2020 20:42:37

US3312187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '14'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:42:37

US3312187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered 'breaths/min'	System	16 Oct 2020 20:42:37

US3312187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '132'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:42:37

US3312187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered 'mmHg'	System	16 Oct 2020 20:42:37

US3312187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '84'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:42:37

US3312187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered 'mmHg'	System	16 Oct 2020 20:42:37

US3312187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01

US3312187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01

US3312187

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:42:42

US3312187

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:42:42

US3312187

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:43:02

US3312187

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:43:02

US3312187

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered '08:50'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:43:02

US3312187

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered '15 Oct 2020 08:50'	System	16 Oct 2020 20:43:02

US3312187

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:05:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:43:07

US3312187

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered '1'	System	16 Oct 2020 20:43:07

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 64'	System	20 Aug 2020 17:07:08

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-10-20T00:01:16', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '4b18d8b8-72a3-426c-b04d-97c789d639c5'	System	20 Oct 2020 05:01:30
User entered 'No (N)'	System	20 Oct 2020 05:01:30

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-10-20T00:01:21', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '4b18d8b8-72a3-426c-b04d-97c789d639c5'	System	20 Oct 2020 05:01:30
User entered 'No (N)'	System	20 Oct 2020 05:01:30

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F49B53D2-BEB4-4F66-974F-A6065F88F484)', Time: '2020-10-20T00:01:24', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '4b18d8b8-72a3-426c-b04d-97c789d639c5' User entered '20 Oct 2020 00:01:24'	System	20 Oct 2020 05:01:30
	System	20 Oct 2020 05:01:30

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 17:07:08

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 17:07:08

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 71'	System	20 Aug 2020 17:07:08

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-10-27T12:43:39', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '0f6279ed-dd77-49d7-99de-731e02c65f5e' User entered 'No (N)'	System	27 Oct 2020 17:43:47
	System	27 Oct 2020 17:43:47

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-10-27T12:43:41', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '0f6279ed-dd77-49d7-99de-731e02c65f5e'	System	27 Oct 2020 17:43:47
User entered 'No (N)'	System	27 Oct 2020 17:43:47

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-10-27T12:43:43', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '0f6279ed-dd77-49d7-99de-731e02c65f5e' User entered '27 Oct 2020 12:43:43'	System	27 Oct 2020 17:43:47
	System	27 Oct 2020 17:43:47

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 17:07:08

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 17:07:08

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 78'	System	20 Aug 2020 17:07:08

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-11-03T00:01:34', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'bad430cf-aede-4e5d-aa3a-4504de416aba'	System	03 Nov 2020 06:01:43
User entered 'No (N)'	System	03 Nov 2020 06:01:43

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-11-03T00:01:36', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'bad430cf-aede-4e5d-aa3a-4504de416aba'	System	03 Nov 2020 06:01:43
User entered 'No (N)'	System	03 Nov 2020 06:01:43

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-11-03T00:01:38', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'bad430cf-aede-4e5d-aa3a-4504de416aba' User entered '03 Nov 2020 00:01:38'	System	03 Nov 2020 06:01:43
	System	03 Nov 2020 06:01:43

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 17:07:08

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 17:07:08

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered 'Day 92'	System	20 Aug 2020 17:07:08

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-11-17T00:07:14', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '518ac4cc-f682-43c7-80e1-94dde095dd80'	System	17 Nov 2020 16:19:15
User entered 'Yes (Y)'	System	17 Nov 2020 16:19:15

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-11-17T00:07:16', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '518ac4cc-f682-43c7-80e1-94dde095dd80'	System	17 Nov 2020 16:19:15
User entered 'No (N)'	System	17 Nov 2020 16:19:15

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[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)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-11-17T00:07:19', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '518ac4cc-f682-43c7-80e1-94dde095dd80'	System	17 Nov 2020 16:19:15
User entered 'No (N)'	System	17 Nov 2020 16:19:15

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[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)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-11-17T00:07:35', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '518ac4cc-f682-43c7-80e1-94dde095dd80'	System	17 Nov 2020 16:19:15
User entered 'Yes (Y)'	System	17 Nov 2020 16:19:15

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Please 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)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-11-17T10:19:03', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '518ac4cc-f682-43c7-80e1-94dde095dd80'	System	17 Nov 2020 16:19:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Nov 2020 16:19:15

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-11-17T10:19:06', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '518ac4cc-f682-43c7-80e1-94dde095dd80' User entered '17 Nov 2020 10:19:06'	System	17 Nov 2020 16:19:15
	System	17 Nov 2020 16:19:15

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 17:07:08

US3312187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:49:23
Data entry locked.	System	20 Aug 2020 17:07:08
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 17:07:08

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-12-01T00:01:26', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '6430697f-2028-465c-8ea0-e86b5c08c6a1' User entered 'No (N)'	System	01 Dec 2020 06:01:36
	System	01 Dec 2020 06:01:36

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-12-01T00:01:28', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '6430697f-2028-465c-8ea0-e86b5c08c6a1' User entered 'No (N)'	System	01 Dec 2020 06:01:36
	System	01 Dec 2020 06:01:36

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-12-01T00:01:30', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '6430697f-2028-465c-8ea0-e86b5c08c6a1' User entered '01 Dec 2020 00:01:30'	System	01 Dec 2020 06:01:36
	System	01 Dec 2020 06:01:36

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-12-08T13:15:35', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '6f1e0dd4-38e5-4b39-9fbe-8d804f2325c9'	System	08 Dec 2020 19:15:43
User entered 'No (N)'	System	08 Dec 2020 19:15:43

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-12-08T13:15:36', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '6f1e0dd4-38e5-4b39-9fbe-8d804f2325c9'	System	08 Dec 2020 19:15:43
User entered 'No (N)'	System	08 Dec 2020 19:15:43

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-12-08T13:15:40', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '6f1e0dd4-38e5-4b39-9fbe-8d804f2325c9' User entered '08 Dec 2020 13:15:40'	System	08 Dec 2020 19:15:43
	System	08 Dec 2020 19:15:43

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-12-12T00:01:14', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '423821fc-55b2-4c8a-96c8-6932a7f0ab7e' User entered 'No (N)'	System	12 Dec 2020 06:01:25
	System	12 Dec 2020 06:01:25

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-12-12T00:01:16', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '423821fc-55b2-4c8a-96c8-6932a7f0ab7e' User entered 'No (N)'	System	12 Dec 2020 06:01:25
	System	12 Dec 2020 06:01:25

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-12-12T00:01:18', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '423821fc-55b2-4c8a-96c8-6932a7f0ab7e' User entered '12 Dec 2020 00:01:18'	System	12 Dec 2020 06:01:25
	System	12 Dec 2020 06:01:25

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-12-19T00:01:37', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '7e36d222-62cd-4362-8e79-9490e655fe47'	System	19 Dec 2020 06:02:13
User entered 'No (N)'	System	19 Dec 2020 06:02:13

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-12-19T00:01:39', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '7e36d222-62cd-4362-8e79-9490e655fe47'	System	19 Dec 2020 06:02:13
User entered 'No (N)'	System	19 Dec 2020 06:02:13

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-12-19T00:01:41', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '7e36d222-62cd-4362-8e79-9490e655fe47' User entered '19 Dec 2020 00:01:41'	System	19 Dec 2020 06:02:13
	System	19 Dec 2020 06:02:13

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-12-26T00:01:19', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '25d4955e-768f-4b65-b331-8098a876a17e' User entered 'No (N)'	System	26 Dec 2020 06:01:41
	System	26 Dec 2020 06:01:41

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-12-26T00:01:26', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '25d4955e-768f-4b65-b331-8098a876a17e' User entered 'No (N)'	System	26 Dec 2020 06:01:41
	System	26 Dec 2020 06:01:41

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2020-12-26T00:01:29', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '25d4955e-768f-4b65-b331-8098a876a17e' User entered '26 Dec 2020 00:01:29'	System	26 Dec 2020 06:01:41
	System	26 Dec 2020 06:01:41

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-01-03T23:05:09', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5c2b0d6d-f414-4a54-9eda-dd955bdd9453'	System	04 Jan 2021 05:05:15
User entered 'No (N)'	System	04 Jan 2021 05:05:15

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-01-03T23:05:11', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5c2b0d6d-f414-4a54-9eda-dd955bdd9453'	System	04 Jan 2021 05:05:15
User entered 'No (N)'	System	04 Jan 2021 05:05:15

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-01-03T23:05:13', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '5c2b0d6d-f414-4a54-9eda-dd955bdd9453'	System	04 Jan 2021 05:05:15
User entered '03 Jan 2021 23:05:13'	System	04 Jan 2021 05:05:15

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-01-09T00:01:09', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'e24e031e-a5d6-4710-b1b5-ae5c7bcf9652'	System	09 Jan 2021 06:01:17
User entered 'No (N)'	System	09 Jan 2021 06:01:17

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-01-09T00:01:10', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'e24e031e-a5d6-4710-b1b5-ae5c7bcf9652'	System	09 Jan 2021 06:01:17
User entered 'No (N)'	System	09 Jan 2021 06:01:17

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-01-09T00:01:12', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'e24e031e-a5d6-4710-b1b5-ae5c7bcf9652' User entered '09 Jan 2021 00:01:12'	System	09 Jan 2021 06:01:17
	System	09 Jan 2021 06:01:17

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-01-16T00:01:24', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '34d73d2c-1ed7-4f35-9df0-a744f28b9f15'	System	16 Jan 2021 06:02:18
User entered 'No (N)'	System	16 Jan 2021 06:02:18

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-01-16T00:01:27', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '34d73d2c-1ed7-4f35-9df0-a744f28b9f15'	System	16 Jan 2021 06:02:18
User entered 'No (N)'	System	16 Jan 2021 06:02:18

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-01-16T00:01:30', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '34d73d2c-1ed7-4f35-9df0-a744f28b9f15'	System	16 Jan 2021 06:02:18
User entered '16 Jan 2021 00:01:30'	System	16 Jan 2021 06:02:18

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-01-24T00:03:26', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'cb2c3b64-ee0b-4771-b533-bc983e6f9e14'	System	24 Jan 2021 08:03:35
User entered 'No (N)'	System	24 Jan 2021 08:03:35

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-01-24T00:03:29', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'cb2c3b64-ee0b-4771-b533-bc983e6f9e14' User entered 'No (N)'	System	24 Jan 2021 08:03:35
	System	24 Jan 2021 08:03:35

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-01-24T00:03:33', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'cb2c3b64-ee0b-4771-b533-bc983e6f9e14' User entered '24 Jan 2021 00:03:33'	System	24 Jan 2021 08:03:35
	System	24 Jan 2021 08:03:35

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-01-30T00:01:29', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '83d13f5a-ca5e-4576-a4c3-d4534d20189f' User entered 'No (N)'	System	30 Jan 2021 06:02:09

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-01-30T00:01:32', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '83d13f5a-ca5e-4576-a4c3-d4534d20189f' User entered 'No (N)'	System	30 Jan 2021 06:02:09

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-01-30T00:01:34', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '83d13f5a-ca5e-4576-a4c3-d4534d20189f' User entered '30 Jan 2021 00:01:34'	System	30 Jan 2021 06:02:09
	System	30 Jan 2021 06:02:09

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-02-06T06:11:44', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'ec328afd-cb31-466e-89fb-42f318d564cb' User entered 'No (N)'	System	06 Feb 2021 12:11:55
	System	06 Feb 2021 12:11:55

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-02-06T06:11:50', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'ec328afd-cb31-466e-89fb-42f318d564cb' User entered 'No (N)'	System	06 Feb 2021 12:11:55

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-02-06T06:11:53', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'ec328afd-cb31-466e-89fb-42f318d564cb' User entered '06 Feb 2021 06:11:53'	System	06 Feb 2021 12:11:55
	System	06 Feb 2021 12:11:55

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-02-13T00:02:22', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '1472f361-737a-4a79-9704-e8ccd817f28a' User entered 'No (N)'	System	13 Feb 2021 06:02:32
	System	13 Feb 2021 06:02:32

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-02-13T00:02:24', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '1472f361-737a-4a79-9704-e8ccd817f28a' User entered 'No (N)'	System	13 Feb 2021 06:02:32
	System	13 Feb 2021 06:02:32

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-02-13T00:02:26', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '1472f361-737a-4a79-9704-e8ccd817f28a' User entered '13 Feb 2021 00:02:26'	System	13 Feb 2021 06:02:32
	System	13 Feb 2021 06:02:32

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-02-20T00:01:09', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'adc10ac2-f3df-4e50-9e79-01a040d74dc5'	System	20 Feb 2021 06:01:34
User entered 'No (N)'	System	20 Feb 2021 06:01:34

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-02-20T00:01:11', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'adc10ac2-f3df-4e50-9e79-01a040d74dc5'	System	20 Feb 2021 06:01:34
User entered 'No (N)'	System	20 Feb 2021 06:01:34

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-02-20T00:01:13', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'adc10ac2-f3df-4e50-9e79-01a040d74dc5'	System	20 Feb 2021 06:01:34
User entered '20 Feb 2021 00:01:13'	System	20 Feb 2021 06:01:34

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-02-27T20:06:52-06:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'df987cda-2512-459f-8b51-03473c707eb2'	System	28 Feb 2021 02:13:45
User entered 'No (N)'	System	28 Feb 2021 02:13:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-02-27T20:06:54-06:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'df987cda-2512-459f-8b51-03473c707eb2'	System	28 Feb 2021 02:13:45
User entered 'No (N)'	System	28 Feb 2021 02:13:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-02-27T20:06:56-06:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'df987cda-2512-459f-8b51-03473c707eb2'	System	28 Feb 2021 02:13:45
User entered '28 Feb 2021 02:06:56'	System	28 Feb 2021 02:13:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-03-06T10:30:56-06:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'c7920500-a7a1-4b2b-8d42-a1624293abb9'	System	06 Mar 2021 16:31:04
User entered 'No (N)'	System	06 Mar 2021 16:31:04

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-03-06T10:30:58-06:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'c7920500-a7a1-4b2b-8d42-a1624293abb9'	System	06 Mar 2021 16:31:04
User entered 'No (N)'	System	06 Mar 2021 16:31:04

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-03-06T10:31:00-06:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'c7920500-a7a1-4b2b-8d42-a1624293abb9' User entered '06 Mar 2021 10:31:00'	System	06 Mar 2021 16:31:04
	System	06 Mar 2021 16:31:04

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-03-13T08:08:36-06:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'b4486065-05a6-4960-b336-811faf81b786'	System	13 Mar 2021 14:08:43
User entered 'No (N)'	System	13 Mar 2021 14:08:43

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-03-13T08:08:38-06:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'b4486065-05a6-4960-b336-811faf81b786'	System	13 Mar 2021 14:08:43
User entered 'No (N)'	System	13 Mar 2021 14:08:43

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-03-13T08:08:40-06:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'b4486065-05a6-4960-b336-811faf81b786'	System	13 Mar 2021 14:08:43
User entered '13 Mar 2021 08:08:40'	System	13 Mar 2021 14:08:43

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-03-20T00:03:33-05:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'd94c5e0a-07e4-4d6d-aa61-21dafd768571'	System	20 Mar 2021 05:03:59
User entered 'No (N)'	System	20 Mar 2021 05:03:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-03-20T00:03:35-05:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'd94c5e0a-07e4-4d6d-aa61-21dafd768571'	System	20 Mar 2021 05:03:59
User entered 'No (N)'	System	20 Mar 2021 05:03:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-03-20T00:03:37-05:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'd94c5e0a-07e4-4d6d-aa61-21dafd768571' User entered '20 Mar 2021 00:03:37'	System	20 Mar 2021 05:03:59
	System	20 Mar 2021 05:03:59

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-03-27T00:03:20-05:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '07ab4a24-560e-443c-bab3-905c16eb444b'	System	27 Mar 2021 05:03:30
User entered 'No (N)'	System	27 Mar 2021 05:03:30

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-03-27T00:03:24-05:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '07ab4a24-560e-443c-bab3-905c16eb444b'	System	27 Mar 2021 05:03:30
User entered 'No (N)'	System	27 Mar 2021 05:03:30

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-03-27T00:03:26-05:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '07ab4a24-560e-443c-bab3-905c16eb444b'	System	27 Mar 2021 05:03:30
User entered '27 Mar 2021 00:03:26'	System	27 Mar 2021 05:03:30

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-04-04T09:43:23-05:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'c0d3ae12-373e-466a-9ddf-0c84c59bd90e'	System	04 Apr 2021 14:43:41
User entered 'No (N)'	System	04 Apr 2021 14:43:41

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-04-04T09:43:26-05:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'c0d3ae12-373e-466a-9ddf-0c84c59bd90e'	System	04 Apr 2021 14:43:41
User entered 'No (N)'	System	04 Apr 2021 14:43:41

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-04-04T09:43:28-05:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'c0d3ae12-373e-466a-9ddf-0c84c59bd90e'	System	04 Apr 2021 14:43:41
User entered '04 Apr 2021 09:43:28'	System	04 Apr 2021 14:43:41

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-04-10T14:48:56-05:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'e6ef7649-0b92-40e5-98d4-c59118b31b0c'	System	10 Apr 2021 19:49:02
User entered 'No (N)'	System	10 Apr 2021 19:49:02

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-04-10T14:48:57-05:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'e6ef7649-0b92-40e5-98d4-c59118b31b0c'	System	10 Apr 2021 19:49:02
User entered 'No (N)'	System	10 Apr 2021 19:49:02

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-04-10T14:48:59-05:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: 'e6ef7649-0b92-40e5-98d4-c59118b31b0c' User entered '10 Apr 2021 14:48:59'	System	10 Apr 2021 19:49:02
	System	10 Apr 2021 19:49:02

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-04-18T00:01:25-05:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '2a7b9d86-94e7-4285-88c0-8cbb3142094f' User entered 'No (N)'	System	18 Apr 2021 05:01:36
	System	18 Apr 2021 05:01:36

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-04-18T00:01:27-05:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '2a7b9d86-94e7-4285-88c0-8cbb3142094f' User entered 'No (N)'	System	18 Apr 2021 05:01:36
	System	18 Apr 2021 05:01:36

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-04-18T00:01:32-05:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '2a7b9d86-94e7-4285-88c0-8cbb3142094f' User entered '18 Apr 2021 00:01:32'	System	18 Apr 2021 05:01:36
	System	18 Apr 2021 05:01:36

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-04-24T00:02:42-05:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '889bece1-f83c-4cad-8865-032fe0371c78'	System	24 Apr 2021 05:03:10
User entered 'No (N)'	System	24 Apr 2021 05:03:10

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-04-24T00:02:44-05:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '889bece1-f83c-4cad-8865-032fe0371c78'	System	24 Apr 2021 05:03:10
User entered 'No (N)'	System	24 Apr 2021 05:03:10

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-04-24T00:02:46-05:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '889bece1-f83c-4cad-8865-032fe0371c78'	System	24 Apr 2021 05:03:10
User entered '24 Apr 2021 00:02:46'	System	24 Apr 2021 05:03:10

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-05-01T00:02:12-05:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '086a1117-d69d-4392-9739-ba7e8447c13e'	System	01 May 2021 05:16:26
User entered 'No (N)'	System	01 May 2021 05:16:26

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-05-01T00:02:14-05:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '086a1117-d69d-4392-9739-ba7e8447c13e'	System	01 May 2021 05:16:26
User entered 'No (N)'	System	01 May 2021 05:16:26

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-05-01T00:02:16-05:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '086a1117-d69d-4392-9739-ba7e8447c13e'	System	01 May 2021 05:16:26
User entered '01 May 2021 00:02:16'	System	01 May 2021 05:16:26

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 23:49:45

US3312187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:49:45
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 23:49:45

US3312187

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:00:21

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:16:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-02-27T20:07:00-06:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '26c88835-33b8-447d-a2a4-938659a3aeb2'	System	28 Feb 2021 02:13:49
User entered 'No (N)'	System	28 Feb 2021 02:13:49

US3312187

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:00:21

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:16:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B500470-C44B-4B03-AB28-678863E23705)', Time: '2021-02-27T20:07:03-06:00', User OID: 'PatientReportedOutcome (US3312187)', ODM File OID: '26c88835-33b8-447d-a2a4-938659a3aeb2' User entered '28 Feb 2021 02:07:03'	System	28 Feb 2021 02:13:49
	System	28 Feb 2021 02:13:49

US3312187

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:54:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 21:04:18

US3312187

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:54:57
User entered '12 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 21:04:18

US3312187

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:54:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Nov 2020 21:04:18

US3312187

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:54:57
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 21:04:18

US3312187

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:03:52

US3312187

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:48:01
User entered 'I'	System	17 Nov 2020 21:03:52

US3312187

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:26:32

US3312187

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:26:32

US3312187

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:26:32

US3312187

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:26:32

US3312187

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:37:30

US3312187

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User entered 'I'	System	28 Dec 2020 17:37:30

US3312187

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:08:42

US3312187

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:08:42

US3312187

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:08:42

US3312187

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:08:42

US3312187

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:08:52

US3312187

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User entered 'I'	System	21 Jan 2021 15:08:52

US3312187

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:44:55

US3312187

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:44:55

US3312187

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:44:55

US3312187

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:44:55

US3312187

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:44:44

US3312187

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User entered 'I'	System	24 Feb 2021 17:44:44

US3312187

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:59:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:17:25

US3312187

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:59:38
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:17:25

US3312187

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:59:38
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:17:25

US3312187

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User entered 'VISIT4'	System	24 Mar 2021 16:17:25

US3312187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:59:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:01:44

US3312187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:59:38
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:01:44

US3312187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:59:38
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:01:44

US3312187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User entered empty.	System	29 Mar 2021 20:01:44

US3312187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:59:38
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:01:44

US3312187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:59:38
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:01:44

US3312187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:59:38
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:01:44

US3312187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:59:38
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:01:44

US3312187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User entered empty.	System	29 Mar 2021 20:01:44

US3312187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:59:38
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:01:44

US3312187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User entered empty.	System	29 Mar 2021 20:01:44

US3312187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:59:38
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:01:44

US3312187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User entered empty.	System	29 Mar 2021 20:01:44

US3312187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:59:38
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:01:44

US3312187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User entered empty.	System	29 Mar 2021 20:01:44

US3312187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53

US3312187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53

US3312187

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:59:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:17:35

US3312187

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:59:38
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:17:35

US3312187

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:17:47

US3312187

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:17:47

US3312187

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '08:32'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:17:47

US3312187

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User entered '24 Mar 2021 08:32'	System	24 Mar 2021 16:17:47

US3312187

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:17:51

US3312187

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:44:53
User entered 'I'	System	24 Mar 2021 16:17:51

US3312187

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:39:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:42:39

US3312187

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:39:51
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:42:39

US3312187

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:39:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:42:39

US3312187

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:39:51
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:42:39

US3312187

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:39:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:42:43

US3312187

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 13:42:43

US3312187

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

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:39

US3312187

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

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:39

US3312187

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

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:39

US3312187

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

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'UNBLND_DECIDE'	System	02 Feb 2021 18:10:39

US3312187

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

Form: Unblinding

Generated On: 09 Jun 2021 17:00:21

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:02

US3312187

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

Form: Unblinding

Generated On: 09 Jun 2021 17:00:21

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:17:35

US3312187

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

Form: Unblinding

Generated On: 09 Jun 2021 17:00:21

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:02

US3312187

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

Form: Unblinding

Generated On: 09 Jun 2021 17:00:21

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:17:35

US3312187

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

Form: Unblinding

Generated On: 09 Jun 2021 17:00:21

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:02

US3312187

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

Form: Unblinding

Generated On: 09 Jun 2021 17:00:21

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:02

US3312187

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

Form: Unblinding

Generated On: 09 Jun 2021 17:00:21

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:02

US3312187

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

Form: Unblinding

Generated On: 09 Jun 2021 17:00:21

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:02

US3312187

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

Form: Unblinding

Generated On: 09 Jun 2021 17:00:21

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:02

US3312187

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

Form: Unblinding

Generated On: 09 Jun 2021 17:00:21

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered '1'	System	02 Feb 2021 18:10:02

US3312187

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

Form: Unblinding

Generated On: 09 Jun 2021 17:00:21

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'I'	System	02 Feb 2021 18:10:02

US3312187

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered empty.	System	02 Feb 2021 18:12:06
DataPoint set to visible.	System	02 Feb 2021 18:10:02

US3312187

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered empty.	System	02 Feb 2021 18:12:06
DataPoint set to visible.	System	02 Feb 2021 18:10:02

US3312187

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '13:53'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered '27 Jan 2021 13:53'	System	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '99.3' F	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '75'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'bpm'	System	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '14'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'breaths/min'	System	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '139'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'mmHg'	System	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '75'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'mmHg'	System	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered empty.	System	02 Feb 2021 18:12:06
DataPoint set to visible.	System	02 Feb 2021 18:10:02

US3312187

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '15:19'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered '27 Jan 2021 15:19'	System	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '64'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'bpm'	System	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '14'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'breaths/min'	System	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '137'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'mmHg'	System	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '80'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:06

US3312187

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'mmHg'	System	02 Feb 2021 18:12:06

US3312187

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:16

US3312187

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:16

US3312187

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

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:29

US3312187

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

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:29

US3312187

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

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:29

US3312187

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

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'mRNA-1273'	System	02 Feb 2021 18:12:29
DataPoint set to visible.	System	02 Feb 2021 18:10:02

US3312187

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

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:29

US3312187

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

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '14:48'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:29

US3312187

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

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered '27 Jan 2021 14:48'	System	02 Feb 2021 18:12:29

US3312187

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

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:29

US3312187

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

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'ONCE'	System	02 Feb 2021 18:12:29

US3312187

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

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'INTRAMUSCULAR'	System	02 Feb 2021 18:12:29

US3312187

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:14

US3312187

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:14

US3312187

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '13:35'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:14

US3312187

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered '27 Jan 2021 13:35'	System	02 Feb 2021 18:10:14

US3312187

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:00:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:21

US3312187

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:00:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:21

US3312187

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:00:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '13:34'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:21

US3312187

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered '27 Jan 2021 13:34'	System	02 Feb 2021 18:10:21

US3312187

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

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:25

US3312187

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

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'I'	System	02 Feb 2021 18:10:25

US3312187

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:46:44

US3312187

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:46:44

US3312187

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:46:44

US3312187

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:46:44

US3312187

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:46:47

US3312187

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'I'	System	24 Feb 2021 17:46:47

US3312187

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered '1'	System	24 Feb 2021 17:46:47
DataPoint set to visible.	System	24 Feb 2021 17:46:47

US3312187

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:28:32

US3312187

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:28:32

US3312187

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:28:32

US3312187

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'OLD29'	System	26 Feb 2021 15:28:32

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '08:51'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered '24 Feb 2021 08:51'	System	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '59'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'bpm'	System	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '12'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'breaths/min'	System	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '118'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'mmHg'	System	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '72'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'mmHg'	System	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '10:16'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered '24 Feb 2021 10:16'	System	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '67'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'bpm'	System	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '16'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'breaths/min'	System	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '132'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'mmHg'	System	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '89'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'mmHg'	System	26 Feb 2021 15:29:30

US3312187

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:30:06

US3312187

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:30:06

US3312187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:30:33

US3312187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:30:33

US3312187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:30:33

US3312187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'mRNA-1273'	System	26 Feb 2021 15:30:33
DataPoint set to visible.	System	24 Feb 2021 17:46:47

US3312187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:30:33

US3312187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '09:45'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:30:33

US3312187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered '24 Feb 2021 09:45'	System	26 Feb 2021 15:30:33

US3312187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:30:33

US3312187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'ONCE'	System	26 Feb 2021 15:30:33

US3312187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'INTRAMUSCULAR'	System	26 Feb 2021 15:30:33

US3312187

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:30:37

US3312187

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'I'	System	26 Feb 2021 15:30:37

US3312187

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:16:05

US3312187

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '03 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:16:05

US3312187

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:16:05

US3312187

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:16:05

US3312187

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:16:09

US3312187

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'I'	System	05 Mar 2021 17:16:09

US3312187

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:18:10

US3312187

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:18:10

US3312187

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:18:10

US3312187

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered 'OLD57'	System	24 Mar 2021 16:18:10

US3312187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:18:21

US3312187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:18:21

US3312187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:18:21

US3312187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered empty.	System	24 Mar 2021 16:18:21

US3312187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:18:21

US3312187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:18:21

US3312187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:18:21

US3312187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:18:21

US3312187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered empty.	System	24 Mar 2021 16:18:21

US3312187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:18:21

US3312187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered empty.	System	24 Mar 2021 16:18:21

US3312187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:18:21

US3312187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered empty.	System	24 Mar 2021 16:18:21

US3312187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:18:21

US3312187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered empty.	System	24 Mar 2021 16:18:21

US3312187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00

US3312187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00

US3312187

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:18:26

US3312187

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:18:26

US3312187

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:18:37

US3312187

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:18:37

US3312187

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '08:32'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:18:37

US3312187

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:00
User entered '24 Mar 2021 08:32'	System	24 Mar 2021 16:18:37

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:00:21

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:57:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '17 Sep 2020'	(b) (4) Karol Moore (b) (4)	06 Oct 2020 17:25:49

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:00:21

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:57:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:25:49

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:00:21

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:57:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:25:49

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:00:21

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:57:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:25:49

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:00:21

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:57:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:25:49

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:26:18

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '17 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:26:18

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '08:14'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:26:18

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:57:49
User entered '17 Sep 2020 08:14'	System	06 Oct 2020 17:26:18

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	06 Oct 2020 17:26:18

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:26:18

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:26:18

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '54'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:26:18

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:57:49
User entered 'bpm'	System	06 Oct 2020 17:26:18

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	06 Oct 2020 17:26:18

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:57:49
User entered 'breaths/min'	System	06 Oct 2020 17:26:18

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	06 Oct 2020 17:26:18

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:57:49
User entered 'mmHg'	System	06 Oct 2020 17:26:18

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:57:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	06 Oct 2020 17:26:18

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:57:49
User entered 'mmHg'	System	06 Oct 2020 17:26:18

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:57:49

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:57:49

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:00:21

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:58:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '17 Sep 2020'	(b) (4) Karol Moore (b) (4)	06 Oct 2020 17:26:28

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:00:21

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:58:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:26:28

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:00:21

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:58:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:26:28

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:00:21

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:58:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:26:28

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:00:21

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:58:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:26:28

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:58:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:26:46

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:58:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '17 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:26:46

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:58:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '09:25'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:26:46

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:58:26
User entered '17 Sep 2020 09:25'	System	06 Oct 2020 17:26:46

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:58:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	06 Oct 2020 17:26:46

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:58:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:26:46

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:58:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:26:46

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:58:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '54'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 17:26:46

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:58:26
User entered 'bpm'	System	06 Oct 2020 17:26:46

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:58:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	06 Oct 2020 17:26:46

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:58:26
User entered 'breaths/min'	System	06 Oct 2020 17:26:46

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:58:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	06 Oct 2020 17:26:46

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:58:26
User entered 'mmHg'	System	06 Oct 2020 17:26:46

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:58:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	06 Oct 2020 17:26:46

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:58:26
User entered 'mmHg'	System	06 Oct 2020 17:26:46

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:58:26

US3312187

Folder: Unscheduled 17 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:58:26

US3312187

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:00:21

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:42:26
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 22:12:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 20:27:54

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:57:31
User entered 'USA-US300-2020-mRNA-1273-P301000014'	System	17 Nov 2020 00:31:53
User entered 'New'	(b) (4), (b) (6)	17 Nov 2020 00:31:53

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:58:04
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Myopathies, PT: Rhabdomyolysis, LLT: Rhabdomyolysis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 23:23:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 23:23:38
Data point term sent to Coder	System	13 Nov 2020 20:32:59
User entered 'rhabdomyolysis'	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:58:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:58:16
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:58:45
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:58:59
User entered '08 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:59:01
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:55:49
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 08:50:10
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 17:55:25
DataPoint Un-verified.	(b) (4), (b) (6)	13 Jan 2021 17:33:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 17:33:08
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 00:56:01
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 18:59:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:55:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	13 Jan 2021 17:55:52
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	13 Jan 2021 17:55:52
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	13 Jan 2021 17:33:08
DataPoint Un-verified.	(b) (4), (b) (6)	13 Jan 2021 17:33:08
User entered '12 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 17:33:08
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 18:59:10
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:59:12
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 15:30:37
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:40:56
User entered empty.	System	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:39:32
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 17:33:08
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 17:33:08
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 18:59:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:39:34
User closed query 'Source says no. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 17:39:25
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
Query 'Source says no. Please review and reconcile. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 17:56:22
User opened query 'Source says no. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 19:00:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:57:17
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:57:15
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
User closed query 'Per CDM: Previous response noted, please leave this query open and update when data becomes available or clarify.' (Site from DM).	(b) (4)	14 Jan 2021 08:50:15
Query 'Per CDM: Previous response noted, please leave this query open and update when data becomes available or clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 17:57:50
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 22:01:59
User opened query 'Per CDM: Previous response noted, please leave this query open and update when data becomes available or clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 20:57:21
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 20:55:57
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'hospitalization ongoing at this time' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 20:33:39
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	13 Nov 2020 20:32:39
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 22:03:10
User entered '12 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:39:47
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 17:57:40
User entered '14 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 17:57:40
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 22:03:22
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 15:31:30
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 20:55:33
User entered '13 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 20:54:51
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:40:44
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 22:04:25
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 22:04:27
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 22:04:29
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 22:04:31
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 22:04:33
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 22:04:54
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 22:04:55
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 22:05:03
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 20:33:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 20:33:57
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 20:33:57
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 20:32:39
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 22:05:06
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 08:50:19
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 23:04:36
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 22:05:30
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 09:32:04
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:39:58
User closed query 'Liver US occurrence documented on 17NOV2020 with a negative result. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 17:39:56
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
Query 'Liver US occurrence documented on 17NOV2020 with a negative result. Please review and reconcile. ' answered with 'Diagnostic test only, not a procedure. Please confirm with medical team that this is necessary. Listed in narrative, not necessary on Con Procedure log per pI' (Site from CRA).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:04:29
User opened query 'Liver US occurrence documented on 17NOV2020 with a negative result. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 22:09:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 22:09:12
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 22:05:32
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:40:02
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
User closed query 'Source does not have selection. Please review and reconcile ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:31:22
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:39:01
Query 'Source does not have selection. Please review and reconcile ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 18:01:12
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 18:01:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 17:55:52
User opened query 'Source does not have selection. Please review and reconcile ' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 22:06:32
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:41:19
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:40:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:32:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:40:11
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:13
User closed query 'PV Query: Please provide results of ALT, AST and CK with nits and normal ranges.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 14:39:12
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:39:07
User closed query 'Per DM CLR: SAE Narrative = FLU, HEPATITS AND MONO VIRUS TESTS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 08:50:44
User closed query 'Per DM CLR: Narrative indicates that subject had LIVER US. However, this is not recorded in the Concomitant Procedure eCRF. Please review and record as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 08:50:43
User closed query 'Per DM CLR: SAE Narrative = SUBJECT ADMITTED FOR FLUIDS. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 08:50:37
Query 'Per DM CLR: SAE Narrative = SUBJECT ADMITTED FOR FLUIDS. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 23:04:40
Query 'Per DM CLR: Narrative indicates that subject had LIVER US. However, this is not recorded in the Concomitant Procedure eCRF. Please review and record as appropriate. Otherwise, clarify.' answered with 'Diagnostic test only, not a procedure. Please confirm with medical team that this is necessary, listed in Narrative-NA in Con PProcedure per PI' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 23:04:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = FLU, HEPATITS AND MONO VIRUS TESTS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Not necessary to list every diagnostic lab test as a Con procedure per PI-Please confirm with medical team if this is necessary' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 23:02:49
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'COVID 19 PCR nasopharygial swab Done 13Nov2020-Negative' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 23:01:42
Query 'PV Query: Please provide results of ALT, AST and CK with nits and normal ranges.' answered with 'see narrative' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 22:59:27
DataPoint Un-verified.	(b) (4), (b) (6)	13 Jan 2021 22:59:11

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Narrative](#)

Audit	User	Time (GMT)
User entered '31 YEAR OLD MALE, NO SIGNIFICANT MEDICAL HISTORY, (b) (6) SOCCER COACH, DOSED 20AUG2020 AND 17SEP2020, DEVELOPED MODERATE BILATERAL ANTERIOR THIGH PAIN ON 08NOV2020 FOR WHICH HE TOOK PRN IBUPROFEN. PAIN SEEMED DISPROPORTIONAL TO ACTIVITY SO SUBJECT SAW PCP 09NOV2020. LABS REVEALED ELEVATED AST, ALT AND FURTHER WORK-UP WAS SCHEDULED, IBUPROFEN DISCONTINUED NO OTHER SYMPTOMS DEVELOPED AND PAIN DOWN TO 1/10 ON 12NOV2020 BUT CK RETURNED "VERY HIGH" AND SUBJECT INSTRUCTED BY PCP TO GO TO ER. SUBJECT ADMITTED FOR FLUIDS; AST, ALT, CK HAVE BEEN COMING DOWN; SUBJECT REPORTS FEELING "GREAT." SAE OF RHABDOMYOLYSIS, NOT RELATED TO IP, PROBABLY PARTIALLY RELATED TO SUBJECT'S SOCCER ACTIVITIES, PERHAPS VIRAL MYOSITIS. WILL PROCURE MEDICAL RECORDS FOR DETAILS AND FURTHER ELUCIDATION. UPDATE: SUBJECT DC FROM HOSPITAL 13NOV2020, LIVER US NEGATIVE, FLU, HEPATITS AND MONO VIRUS TESTS NEGATIVE,OVEREXERTION DUE TO SOCCER IN SETTING OF DEHYDRATION RHABDO. HAS INCREASE WATER INTAKE AND HAS FOLLOW UP WITH PCP THIS WEEK. MEDICAL RECORDS PENDING. Update 13Jan2021:Medical records reviewed and confirm subject's report of hospitalization for iv fluids treatment for rhabdomyolysis related to overexertion involving bilateral quadriceps. Subject admitted 12Nov20 and discharged 14Nov20. In hospital labs showed CK >20K, AST 1137, ALT 306 on admit and 1672, 548, and 223 before discharge, respectively. Liver ultrasound, hepatitis panel, kidney function tests, acetaminophen levels, and Covid test were unremarkable or negative. Subject increased	(b) (4), (b) (6)	13 Jan 2021 22:59:11

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Narrative](#)

Audit	User	Time (GMT)
hydration, moderated exercise, has felt well, and reports that at f/u with PCP on 02Dec2020 CK, AST and ALT were 2686, 82, and 50 respectively and no further work-up plan.SAE of rhabdomyolysis, NR to IP, G3, resolved' reason for change: Data Entry Error		
User opened query 'Per DM CLR: SAE Narrative = FLU, HEPATITS AND MONO VIRUS TESTS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 00:55:33
User opened query 'Per DM CLR: SAE Narrative = SUBJECT ADMITTED FOR FLUIDS. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 00:55:26
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 22:10:32
User opened query 'Per DM CLR: Narrative indicates that subject had LIVER US. However, this is not recorded in the Concomitant Procedure eCRF. Please review and record as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 09:32:10
User opened query 'PV Query: Please provide results of ALT, AST and CK with nits and normal ranges.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 21:14:13
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:42:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Narrative](#)

Audit	User	Time (GMT)
User entered '31 YEAR OLD MALE, NO SIGNIFICANT MEDICAL HISTORY, (b) (6) SOCCER COACH, DOSED 20AUG2020 AND 17SEP2020, DEVELOPED MODERATE BILATERAL ANTERIOR THIGH PAIN ON 08NOV2020 FOR WHICH HE TOOK PRN IBUPROFEN. PAIN SEEMED DISPROPORTIONAL TO ACTIVITY SO SUBJECT SAW PCP 09NOV2020. LABS REVEALED ELEVATED AST, ALT AND FURTHER WORK-UP WAS SCHEDULED, IBUPROFEN DISCONTINUED NO OTHER SYMPTOMS DEVELOPED AND PAIN DOWN TO 1/10 ON 12NOV2020 BUT CK RETURNED "VERY HIGH" AND SUBJECT INSTRUCTED BY PCP TO GO TO ER. SUBJECT ADMITTED FOR FLUIDS; AST, ALT, CK HAVE BEEN COMING DOWN; SUBJECT REPORTS FEELING "GREAT." SAE OF RHABDOMYOLYSIS, NOT RELATED TO IP, PROBABLY PARTIALLY RELATED TO SUBJECT'S SOCCER ACTIVITIES, PERHAPS VIRAL MYOSITIS. WILL PROCURE MEDICAL RECORDS FOR DETAILS AND FURTHER ELUCIDATION. UDate: Subject DC from hospital 13nov2020, liver US negative, flu, hepatitis and mono virus tests negative, overexertion due to soccer in setting of dehydration rhabdo. has increase water intake and has follow up with PCP this week. Medical records pending.' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 23:43:47

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Narrative](#)

Audit	User	Time (GMT)
User entered '31 year old male, no significant medical history, (b) (6) soccer coach, dosed 20AUG2020 and 17Sep2020, developed moderate bilateral anterior thigh pain on 08Nov2020 for which he took prn ibuprofen. Pain seemed disproportional to activity so subject saw PCP 09Nov2020. Labs revealed elevated AST, ALT and further work-up was scheduled, ibuprofen discontinued No other symptoms developed and pain down to 1/10 on 12Nov2020 but CK returned "very high" and subject instructed by PCP to go to ER. Subject admitted for fluids; AST, ALT, CK have been coming down; subject reports feeling "great." SAE of rhabdomyolysis, not related to IP, probably partially related to subject's soccer activities, perhaps viral myositis. Will procure medical records for details and further elucidation.'	(b) (4), (b) (6)	13 Nov 2020 20:32:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Nov 2020 20:32:39

US3312187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 20:32:39

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:00:21

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:42:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User closed query 'Per ETRTR: According to EDC, Medication was taken for Event "RHABDOMYOLISIS". Please update.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:09:44
User closed query 'Per source, subject took ibuprofen 08NOV2020- 09NOV2020. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 01:12:59
Query 'Per source, subject took ibuprofen 08NOV2020- 09NOV2020. Please review and reconcile. ' answered with 'SEE AE #1' (Site from CRA).	Karol Moore (b) (4) (b) (4)	23 Dec 2020 14:49:53
Query 'Per ETRTR: According to EDC, Medication was taken for Event "RHABDOMYOLISIS". Please update.' answered with 'SEE AE #1' (Site from CRA).	Karol Moore (b) (4) (b) (4)	23 Dec 2020 14:49:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	23 Dec 2020 14:49:35
User opened query 'Per source, subject took ibuprofen 08NOV2020- 09NOV2020. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 22:11:53
User opened query 'Per ETRTR: According to EDC, Medication was taken for Event "RHABDOMYOLISIS". Please update.' (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 19:49:19
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	27 Aug 2020 00:01:11

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:21

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Dec 2020 16:01:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 16:01:50
Data point term sent to Coder	System	23 Dec 2020 14:51:23
User entered 'IBUPROFEN'	Karol Moore (b) (4) (b) (4)	23 Dec 2020 14:50:49

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	23 Dec 2020 14:50:49
	(b) (4)	

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
	(b) (4)	
User entered 'RHABDOMYLOYSIS'	Karol Moore (b) (4)	23 Dec 2020 14:50:49
	(b) (4)	

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
	(b) (4)	
User entered '400'	Karol Moore (b) (4)	23 Dec 2020 14:50:49
	(b) (4)	

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	23 Dec 2020 14:50:49
	(b) (4)	

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	23 Dec 2020 14:50:49
	(b) (4)	

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
	(b) (4)	
User entered 'as needed (PRN)'	Karol Moore (b) (4)	23 Dec 2020 14:50:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	23 Dec 2020 14:50:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	23 Dec 2020 14:50:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	23 Dec 2020 14:50:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
	(b) (4)	
User entered '08 Nov 2020'	Karol Moore (b) (4)	23 Dec 2020 14:50:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	23 Dec 2020 14:50:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	23 Dec 2020 14:50:49
	(b) (4)	

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
	(b) (4)	
User entered '09 Nov 2020'	Karol Moore (b) (4)	23 Dec 2020 14:50:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	23 Dec 2020 14:50:49
	(b) (4)	

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Dec 2020 14:50:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Dec 2020 14:50:49

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Dec 2020 14:50:49

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:17:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:17:54
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 20:58:59
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 16:54:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 16:54:01
Data point term sent to Coder	System	13 Jan 2021 23:06:23
User entered 'sodium chloride 0.9%'	(b) (4), (b) (6)	13 Jan 2021 23:06:04

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:06:04

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'rhabdomyolosis'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:06:04

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '1000'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:06:04

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:06:04

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:06:04

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:06:04

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:06:04

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:06:04

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:06:04

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:06:04

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:06:04

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:06:04

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '14 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:06:04

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:06:04

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:02
User entered empty.	System	13 Jan 2021 23:06:04

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:02
User entered empty.	System	13 Jan 2021 23:06:04

US3312187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:02
User entered empty.	System	13 Jan 2021 23:06:04

US3312187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:00:21

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:54:14

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:03:32
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'USA-US300-2020-MRNA-1273-P301000014'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:38:10
User closed query 'Source states no. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 17:38:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
Query 'Source states no. Please review and reconcile. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 19:44:47
User opened query 'Source states no. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 19:04:26
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'Yes (Y)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:04:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'No (N)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:04:30
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'No (N)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:04:59
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'Yes (Y)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:01
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'No (N)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:03
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'No (N)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:06
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'No (N)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:08
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'Carlos'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:10
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'Fierro'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:11
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered '16300 College Blvd'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:38:29
User closed query 'Site is located in Lenexa. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 17:38:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
Query 'Site is located in Lenexa. Please review and reconcile. ' answered with 'udpated' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 19:44:53
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 19:44:17
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 19:44:17
User opened query 'Site is located in Lenexa. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 19:05:34
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'Shawnee'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:06:51
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'KS'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:06:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered '66219'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:06:54
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 15:31:42
User entered 'US'	System	17 Nov 2020 00:32:09

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Jan 2021 14:39:41
User entered '3'	System	18 Dec 2020 15:31:52
User entered '2'	System	19 Nov 2020 21:47:26
User entered '1'	System	17 Nov 2020 00:32:09

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:03:32
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'USA-US300-2020-MRNA-1273-P301000014'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:38:10
User closed query 'Source states no. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 17:38:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
Query 'Source states no. Please review and reconcile. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 19:44:47
User opened query 'Source states no. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 19:04:26
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'Yes (Y)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:04:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'No (N)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:04:30
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'No (N)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:04:59
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'Yes (Y)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:01
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'No (N)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:03
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'No (N)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:06
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'No (N)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:08
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'Carlos'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:10
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'Fierro'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:11
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered '16300 College Blvd'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:38:29
User closed query 'Site is located in Lenexa. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 17:38:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
Query 'Site is located in Lenexa. Please review and reconcile. ' answered with 'udpated' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 19:44:53
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 19:44:17
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 19:44:17
User opened query 'Site is located in Lenexa. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 19:05:34
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'Shawnee'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:06:51
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'KS'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:06:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered '66219'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:06:54
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 15:31:42
User entered 'US'	System	17 Nov 2020 00:32:09

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Jan 2021 14:39:41
User entered '3'	System	18 Dec 2020 15:31:52
User entered '2'	System	19 Nov 2020 21:47:26
User entered '1'	System	17 Nov 2020 00:32:09

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:00:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:25:57
User entered '17/Nov/2020 00:32'	System	17 Nov 2020 00:32:09

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:00:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:25:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 15:31:42
User entered 'I'	(b) (4), (b) (6)	17 Nov 2020 00:32:09

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:03:32
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'USA-US300-2020-MRNA-1273-P301000014'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:38:10
User closed query 'Source states no. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 17:38:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
Query 'Source states no. Please review and reconcile. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 19:44:47
User opened query 'Source states no. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 19:04:26
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'Yes (Y)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:04:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'No (N)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:04:30
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'No (N)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:04:59
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'Yes (Y)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:01
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'No (N)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:03
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'No (N)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:06
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'No (N)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:08
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'Carlos'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:10
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'Fierro'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:11
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered '16300 College Blvd'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:38:29
User closed query 'Site is located in Lenexa. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 17:38:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
Query 'Site is located in Lenexa. Please review and reconcile. ' answered with 'udpated' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 19:44:53
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 19:44:17
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 19:44:17
User opened query 'Site is located in Lenexa. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 19:05:34
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'Shawnee'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:06:51
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'KS'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:06:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered '66219'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:06:54
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 15:31:42
User entered 'US'	System	17 Nov 2020 00:32:09

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Jan 2021 14:39:41
User entered '3'	System	18 Dec 2020 15:31:52
User entered '2'	System	19 Nov 2020 21:47:26
User entered '1'	System	17 Nov 2020 00:32:09

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:00:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:26:49
User entered '19/Nov/2020 16:47'	System	19 Nov 2020 21:47:26

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:00:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:26:51
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 15:31:42
User entered 'I'	(b) (4), (b) (6)	19 Nov 2020 21:47:26

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:03:32
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'USA-US300-2020-MRNA-1273-P301000014'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:38:10
User closed query 'Source states no. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 17:38:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
Query 'Source states no. Please review and reconcile. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 19:44:47
User opened query 'Source states no. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 19:04:26
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'Yes (Y)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:04:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'No (N)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:04:30
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'No (N)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:04:59
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'Yes (Y)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:01
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'No (N)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:03
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'No (N)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:06
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'No (N)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:08
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'Carlos'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:10
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'Fierro'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:11
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered '16300 College Blvd'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:38:29
User closed query 'Site is located in Lenexa. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 17:38:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
Query 'Site is located in Lenexa. Please review and reconcile. ' answered with 'udpated' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 19:44:53
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 19:44:17
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 19:44:17
User opened query 'Site is located in Lenexa. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 19:05:34
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'Shawnee'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:06:51
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'KS'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:06:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered '66219'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:06:54
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 15:31:42
User entered 'US'	System	17 Nov 2020 00:32:09

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Jan 2021 14:39:41
User entered '3'	System	18 Dec 2020 15:31:52
User entered '2'	System	19 Nov 2020 21:47:26
User entered '1'	System	17 Nov 2020 00:32:09

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:00:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:26:56
User entered '18/Dec/2020 15:31'	System	18 Dec 2020 15:31:52

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:00:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:39:28
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 19:26:58
User entered 'I'	(b) (4), (b) (6)	18 Dec 2020 15:31:52

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:03:32
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'USA-US300-2020-MRNA-1273-P301000014'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:38:10
User closed query 'Source states no. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 17:38:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
Query 'Source states no. Please review and reconcile. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 19:44:47
User opened query 'Source states no. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 19:04:26
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'Yes (Y)'	System	17 Nov 2020 00:31:53

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:04:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'No (N)'	System	17 Nov 2020 00:31:53

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:04:30
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'No (N)'	System	17 Nov 2020 00:31:53

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:04:59
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'Yes (Y)'	System	17 Nov 2020 00:31:53

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:01
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'No (N)'	System	17 Nov 2020 00:31:53

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:03
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'No (N)'	System	17 Nov 2020 00:31:53

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:06
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'No (N)'	System	17 Nov 2020 00:31:53

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:08
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'Carlos'	System	17 Nov 2020 00:31:53

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:10
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'Fierro'	System	17 Nov 2020 00:31:53

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[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:05:11
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered '16300 College Blvd'	System	17 Nov 2020 00:31:53

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Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:38:29
User closed query 'Site is located in Lenexa. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 17:38:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
Query 'Site is located in Lenexa. Please review and reconcile. ' answered with 'udpated' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 19:44:53
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 19:44:17
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 19:44:17
User opened query 'Site is located in Lenexa. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 19:05:34
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'Shawnee'	System	17 Nov 2020 00:31:53

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[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:06:51
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered 'KS'	System	17 Nov 2020 00:31:53

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[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:06:53
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 00:32:02
User entered '66219'	System	17 Nov 2020 00:31:53

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:06:54
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 15:31:42
User entered 'US'	System	17 Nov 2020 00:32:09

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Jan 2021 14:39:41
User entered '3'	System	18 Dec 2020 15:31:52
User entered '2'	System	19 Nov 2020 21:47:26
User entered '1'	System	17 Nov 2020 00:32:09

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:00:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:38:56
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered '14/Jan/2021 09:39'	(b) (4) System	14 Jan 2021 14:39:41

US3312187

Folder: SAE USA-US300-2020-MRNA-1273-P301000014

Form: Safety Report Form (4)

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Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:38:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 20:58:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 14:39:41