

US3212181 (Prod: DM Clinical Research - ERN - PPDS)

Generated By: KC Joubran

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US3212181

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 20:07:58

Generated On: 09 Jun 2021 15:48:57

Participant ID

US3212181

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

US3212181

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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

US3212181

Folder: Screening

Form: Demographics

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	57
Age Units	YEARS
Age (Derived)	57
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) 02 Apr 2021 20:07:59

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Date of Informed Consent (<i>dd MMM yyyy</i>)	14 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) 02 Apr 2021 20:07:59

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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) 02 Apr 2021 20:07:59

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 02 Apr 2021 20:07:59

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Condition	DEPRESSION
Start date (dd MMM yyyy)	UN FEB 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN SEP 2016
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2016
Start Year (derived)	2016
Stop Month and Year (derived)	SEP 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:07:59

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	11:54 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 11:54
Height (xxx.x)	74 in
Weight (xxx.x)	175.8 lb
BMI (xxx.x)	22.61858 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:07:59

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 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) 02 Apr 2021 20:07:59

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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

OIL AND GAS CONSULTANT

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) 02 Apr 2021 20:07:59

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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	PARTICIPANT INTERACTS WITH 5 OR MORE PEOPLE IN PERSON DURING THE COURSE OF A TYPICAL WORKDAY. PARTICIPANT ATTENDED LARGE GROUP EVENTS IN THE PAST FEW WEEKS (E.G., WEDDING, PLACES OF WORSHIP, CONCERT).

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:08:00

Generated On: 09 Jun 2021 15:48:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

What was the date of randomization? (dd MMM yyyy) 14 AUG 2020

What was the participant's randomization number? 104356

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) 02 Apr 2021 20:08:00

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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) 02 Apr 2021 20:08:00

Generated On: 09 Jun 2021 15:48:57

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)	14 AUG 2020
Time of assessment (00:00-23:59)	11:54 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 11:54
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 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) 02 Apr 2021 20:08:00

Generated On: 09 Jun 2021 15:48:57

Height	ND - Not Done
Weight	ND - Not Done
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)	14 AUG 2020
Time of assessment (00:00-23:59)	15:47 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 15:47
Temperature (xxx.x)	96.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

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) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

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) 14 AUG 2020

What was the treatment time? (00:00-23:59) 14:56 (24 HR)

Treatment Date and Time (derived) 14 AUG 2020 14:56

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

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

Collection date (dd MMM yyyy)	14 AUG 2020
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Collection time (00:00-23:59)	12:45 (24 HR)
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Collection date and time (derived)	14 AUG 2020 12:45
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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Collection date (dd MMM yyyy)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:40	14 AUG 2020 12:40
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

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

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 15:42

PC Open Date & Time

14 AUG 2020 15:16

PC Close Date & Time

14 AUG 2020 17:46

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

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	14 AUG 2020 18:47
PC Open Date & Time	14 AUG 2020 18:41
PC Close Date & Time	15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:48:57

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

97.1 °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

15 AUG 2020 19:25

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

16 AUG 2020 18:49

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:48:57

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

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

17 AUG 2020 18:08

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:48:57

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 18:04

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:48:57

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

96.3 °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

19 AUG 2020 21:31

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:48:57

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

95.6 °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

20 AUG 2020 18:38

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

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

14 AUG 2020 15:43

PC Open Date & Time

14 AUG 2020 15:16

PC Close Date & Time

14 AUG 2020 17:46

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

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

14 AUG 2020 18:45

PC Open Date & Time

14 AUG 2020 18:41

PC Close Date & Time

15 AUG 2020 11:59

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:48:57

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

15 AUG 2020 19:26

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:48:57

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

16 AUG 2020 18:50

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:48:57

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

17 AUG 2020 18:09

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:48:57

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

18 AUG 2020 18:03

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:48:57

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

19 AUG 2020 21:30

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:48:57

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

20 AUG 2020 18:37

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 15:44
PC Open Date & Time	14 AUG 2020 15:16
PC Close Date & Time	14 AUG 2020 17:46

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 18:46
PC Open Date & Time	14 AUG 2020 18:41
PC Close Date & Time	15 AUG 2020 11:59

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

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 ☒

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 19:27
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

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 ☒

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 18:50
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

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

46 of 2063

EAB) (1725)

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 18:09
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

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 ☒

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 18:04
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

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

50 of 2063

EAB) (1725)

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 21:30
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2063

EAB) (1725)

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 18:37
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3212181

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3212181

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212181

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3212181

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212181

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 4 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3212181

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212181

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:08:00

Generated On: 09 Jun 2021 15:48:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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	VISIT2

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 20:08:00

Generated On: 09 Jun 2021 15:48:57

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)	02 OCT 2020
Time of assessment (00:00-23:59)	11:45 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 11:45
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 20:08:00

Generated On: 09 Jun 2021 15:48:57

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)	02 OCT 2020
Time of assessment (00:00-23:59)	14:17 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 14:17
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3212181

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:08:00

Generated On: 09 Jun 2021 15:48:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 OCT 2020

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

US3212181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 20:08:00

Generated On: 09 Jun 2021 15:48:57

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) 02 OCT 2020

What was the treatment time? (00:00-23:59) 13:36 (24 HR)

Treatment Date and Time (derived) 02 OCT 2020 13:36

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

What was the frequency of the study treatment dosing? ONCE

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

US3212181

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:08:00

Generated On: 09 Jun 2021 15:48:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 OCT 2020
Collection time (00:00-23:59)	12:44 (24 HR)
Collection date and time (derived)	02 OCT 2020 12:44

US3212181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 02 Apr 2021 20:08:00

Generated On: 09 Jun 2021 15:48:57

Collection date (dd MMM yyyy)			02 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:39	02 OCT 2020 12:39
Nasopharyngeal Swab 2	No		

US3212181

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:08:00

Generated On: 09 Jun 2021 15:48:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

02 OCT 2020 14:19

PC Open Date & Time

02 OCT 2020 13:56

PC Close Date & Time

02 OCT 2020 16:26

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

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 95.6 °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	02 OCT 2020 17:29
PC Open Date & Time	02 OCT 2020 17:21
PC Close Date & Time	03 OCT 2020 11:59

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:48:57

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

97.9 °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

04 OCT 2020 09:37

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 09:45

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 09:07

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:48:57

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

97.6 °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

06 OCT 2020 17:06

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:48:57

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 12:02

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:48:57

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

97.5 °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

08 OCT 2020 12:01

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

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

02 OCT 2020 14:19

PC Open Date & Time

02 OCT 2020 13:56

PC Close Date & Time

02 OCT 2020 16:26

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

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

02 OCT 2020 17:28

PC Open Date & Time

02 OCT 2020 17:21

PC Close Date & Time

03 OCT 2020 11:59

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:48:57

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

04 OCT 2020 09:36

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:48:57

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

05 OCT 2020 09:44

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:48:57

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

06 OCT 2020 09:07

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:48:57

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

06 OCT 2020 17:06

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:48:57

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

07 OCT 2020 12:00

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:48:57

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

08 OCT 2020 12:01

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 14:19
PC Open Date & Time	02 OCT 2020 13:56
PC Close Date & Time	02 OCT 2020 16:26

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 17:28
PC Open Date & Time	02 OCT 2020 17:21
PC Close Date & Time	03 OCT 2020 11:59

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

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 ☒

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 09:36
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

90 of 2063

EAB) (1725)

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 09:44
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

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 ☒

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 09:08
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

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

94 of 2063

EAB) (1725)

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 17:08
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

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)

96 of 2063

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 12:01
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

98 of 2063

EAB) (1725)

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 12:02
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3212181

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3212181

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212181

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212181

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212181

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3212181

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212181

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:11:56

Generated On: 09 Jun 2021 15:48:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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

US3212181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:11:56

Generated On: 09 Jun 2021 15:48:57

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	12:23 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 12:23
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212181

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:08:00

Generated On: 09 Jun 2021 15:48:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 OCT 2020

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

US3212181

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:08:00

Generated On: 09 Jun 2021 15:48:57

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 OCT 2020

Collection time (00:00-23:59)

12:52 (24 HR)

Collection date and time (derived)

27 OCT 2020 12:52

US3212181

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:08:00

Generated On: 09 Jun 2021 15:48:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 OCT 2020 17:17:38

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

21 OCT 2020 09:06:03

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 14:42:16

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 09:35:27

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 14:37:17

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

22 NOV 2020 00:02:14

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

30 NOV 2020 08:35:58

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

06 DEC 2020 14:18:48

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

14 DEC 2020 16:11:54

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

21 DEC 2020 08:12:06

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

28 DEC 2020 11:17:43

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

03 JAN 2021 09:44:50

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

11 JAN 2021 09:26:58

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

19 JAN 2021 12:46:05

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 JAN 2021 10:12:11

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

31 JAN 2021 09:57:42

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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	08 FEB 2021 12:53:56
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

14 FEB 2021 10:26:43

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 <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	21 FEB 2021 00:01:56
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 08:14:49

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

07 MAR 2021 00:22:32

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

18 MAR 2021 13:52:03

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

22 MAR 2021 10:23:36

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 229

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

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

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

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 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	08 APR 2021 16:10:38
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

11 APR 2021 17:33:38

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 18:05:07

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

25 APR 2021 20:02:28

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 00:02:36

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 <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"/>

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 278

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

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

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

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

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

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

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 285

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

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

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

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

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

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

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 292

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

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

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

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

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

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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"/>

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐
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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 <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"/>

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 348

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

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

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

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

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

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

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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°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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 369

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	23 SEP 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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"/>

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	21 OCT 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 439

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

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

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

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

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

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

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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°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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐
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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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="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"/>

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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	14 NOV 2021 00:01
Patient Cloud Close Date & Time	18 NOV 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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"/>

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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°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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	09 DEC 2021 23:59
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US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 488

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

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

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

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

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

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

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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°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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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°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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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°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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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°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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	17 MAR 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	24 MAR 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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="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"/>

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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"/>

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 614

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

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

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

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

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

Fever (Temperature \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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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"/>

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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"/>

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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°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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 670

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

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

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

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

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

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

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	30 JUN 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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"/>

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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°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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 719

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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°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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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°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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 740

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

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

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

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

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

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 747

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 754

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

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

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

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

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

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

DAY 768

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

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

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

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

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

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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	09 OCT 2022 00:01
Patient Cloud Close Date & Time	13 OCT 2022 23:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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"/>

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3212181

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:48:57

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		01 MAR 2021 08:15:34

US3212181

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212181

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212181

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212181

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212181

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3212181

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212181

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 02 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3212181

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212181

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:11:56

Generated On: 09 Jun 2021 15:48:57

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

Visit date (dd MMM yyyy)	23 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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US3212181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:11:56

Generated On: 09 Jun 2021 15:48:57

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 MAR 2021
Time of assessment (00:00-23:59)	13:19 (24 HR)
Vital Signs Date and Time (derived)	23 MAR 2021 13:19
Temperature (xxx.x)	97.2 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212181

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:11:56

Generated On: 09 Jun 2021 15:48:57

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.

US3212181

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:11:56

Generated On: 09 Jun 2021 15:48:57

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

Collection date (dd MMM yyyy)	23 MAR 2021
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Collection time (00:00-23:59)	14:04 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	23 MAR 2021 14:04
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US3212181

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:11:56

Generated On: 09 Jun 2021 15:48:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212181

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 01 May 2021 18:40:46

Generated On: 09 Jun 2021 15:48:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212181

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 01 May 2021 18:40:46

Generated On: 09 Jun 2021 15:48:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212181

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

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

US3212181

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 20:07:58

Generated On: 09 Jun 2021 15:48:57

Date of Contact	18 SEP 2020
Time of Contact	14:02
Date and Time of Contact (derived)	18 SEP 2020 14:02
Type of Contact	<div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input checked="" type="checkbox"/></div> <div>Safety Call <input type="checkbox"/></div> <div>Convalescent Tele-visit <input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="checkbox"/></div> <div>No <input type="checkbox"/></div>

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 20:07:58

Generated On: 09 Jun 2021 15:48:57

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 20:07:58

Generated On: 09 Jun 2021 15:48:57

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	18 SEP 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

313 of 2063

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 20:07:58

Generated On: 09 Jun 2021 15:48:57

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 20:07:58

Generated On: 09 Jun 2021 15:48:57

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 02 Apr 2021 20:07:58

Generated On: 09 Jun 2021 15:48:57

Date of Visit	18 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	18 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 02 Apr 2021 20:07:58

Generated On: 09 Jun 2021 15:48:57

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3212181

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

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

Visit date (dd MMM yyyy)	21 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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US3212181

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 19:29:31

Generated On: 09 Jun 2021 15:48:57

Date of updated informed consent (<i>dd MMM yyyy</i>)	21 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>)	21 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

US3212181

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

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

US3212181

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

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)	21 JAN 2021
Time of assessment (00:00-23:59)	10:51 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 10:51
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 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)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3212181

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

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)	21 JAN 2021
Time of assessment (00:00-23:59)	12:53 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 12:53
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3212181

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 JAN 2021

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

US3212181

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

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) 21 JAN 2021

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

Treatment Date and Time (derived) 21 JAN 2021 12:23

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

What was the frequency of the study treatment dosing? ONCE

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

US3212181

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

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

Collection date (dd MMM yyyy)	21 JAN 2021
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Collection time (00:00-23:59)	11:32 (24 HR)
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Collection date and time (derived)	21 JAN 2021 11:32
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US3212181

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 JAN 2021

Collection time (00:00 - 23:59)

11:28

Collection Date and Time (derived)

21 JAN 2021 11:28

US3212181

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212181

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212181

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

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

US3212181

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:07:58

Generated On: 09 Jun 2021 15:48:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

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)	23 FEB 2021
Time of assessment (00:00-23:59)	12:05 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 12:05
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

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)	23 FEB 2021
Time of assessment (00:00-23:59)	13:26 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 13:26
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)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3212181

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:07:58

Generated On: 09 Jun 2021 15:48:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 FEB 2021

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

US3212181

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 20:07:58

Generated On: 09 Jun 2021 15:48:57

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) 23 FEB 2021

What was the treatment time? (00:00-23:59) 12:56 (24 HR)

Treatment Date and Time (derived) 23 FEB 2021 12:56

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

What was the frequency of the study treatment dosing? ONCE

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

US3212181

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:07:58

Generated On: 09 Jun 2021 15:48:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212181

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 02 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3212181

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212181

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

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

Visit date (dd MMM yyyy)	23 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	OLD57
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US3212181

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	13:19 (24 HR)
Vital Signs Date and Time (derived)	23 MAR 2021 13:19
Temperature (<i>xxx.x</i>)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	62 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212181

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 MAR 2021

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

US3212181

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 MAR 2021
Collection time (00:00-23:59)	14:04 (24 HR)
Collection date and time (derived)	23 MAR 2021 14:04

US3212181

Folder: **Unscheduled 18 Sep 2020**

Form: **Unscheduled Visit Assessment**

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Visit Date	18 SEP 2020
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	False
Immunogenicity Assessment	True
Pregnancy Test	False

US3212181

Folder: Unscheduled 18 Sep 2020

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:07:59

Generated On: 09 Jun 2021 15:48:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 SEP 2020
Collection time (00:00-23:59)	14:03 (24 HR)
Collection date and time (derived)	18 SEP 2020 14:03

US3212181

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 02 Apr 2021 20:07:58

Generated On: 09 Jun 2021 15:48:57

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

AEID	USA-US115-2021-MRNA-1273-P30 1000017
Adverse event	WORSENING OF DEPRESSION
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)	05 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
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)	24 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	08 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

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 <input type="radio"/> 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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT NOTIFIED THE SITE THAT HE IS ADMITTED TO THE HOSPITAL FOR TREATMENT.
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)	

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

AEID	
Adverse event	INSOMNIA
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)	05 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input 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 checked="" type="radio"/> Recovered/Resolved <input 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 _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

AEID	
Adverse event	ANXIETY
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)	24 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input 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 checked="" type="radio"/> Recovered/Resolved <input 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 _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 20:07:58

Generated On: 09 Jun 2021 15:48:57

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

Yes ☒

No ☐

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

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 19:10:42

Generated On: 09 Jun 2021 15:48:57

Name of Medication INFLUENZA VACCINATION

Prophylaxis Yes ☒
No ☐

Indication IMMUNIZATION

Dose per administration 0.5

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

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 19:10:42

Generated On: 09 Jun 2021 15:48:57

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		22 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 19:10:42

Generated On: 09 Jun 2021 15:48:57

Name of Medication ESCITALOPRAM

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF DEPRESSION

Dose per administration 10

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

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 19:10:42

Generated On: 09 Jun 2021 15:48:57

	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)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 19:10:42

Generated On: 09 Jun 2021 15:48:57

Name of Medication TRAZODONE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 50

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

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 19:10:42

Generated On: 09 Jun 2021 15:48:57

	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)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 19:10:42

Generated On: 09 Jun 2021 15:48:57

Name of Medication CYMBALTA

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION/ANXIETY

Dose per administration 90

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

358 of 2063

EAB) (1725)

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 19:10:42

Generated On: 09 Jun 2021 15:48:57

	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)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 19:10:42

Generated On: 09 Jun 2021 15:48:57

Name of Medication LITHIUM CARBONATE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION/ANXIETY

Dose per administration 300

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

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 19:10:42

Generated On: 09 Jun 2021 15:48:57

	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)	8 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 19:10:42

Generated On: 09 Jun 2021 15:48:57

Name of Medication ABILIFY

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION/ANXIETY

Dose per administration 5

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

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 19:10:42

Generated On: 09 Jun 2021 15:48:57

	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)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 19:10:42

Generated On: 09 Jun 2021 15:48:57

Name of Medication REMERON

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION/ANXIETY

Dose per administration 30

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

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 19:10:42

Generated On: 09 Jun 2021 15:48:57

	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)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3212181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 20:07:58

Generated On: 09 Jun 2021 15:48:57

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3212181

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:48:57

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

US3212181

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:48:57

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 ☐

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 19:10:42

Generated On: 09 Jun 2021 15:48:57

SAEID	USA-US115-2021-MRNA-1273-P301000017
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	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 19:10:42

Generated On: 09 Jun 2021 15:48:57

SAEID	USA-US115-2021-MRNA-1273-P301000017
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	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	26/MAR/2021 10:00
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 19:10:42

Generated On: 09 Jun 2021 15:48:57

SAEID	USA-US115-2021-MRNA-1273-P301000017
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	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	06/APR/2021 12:26
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

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 19:10:42

Generated On: 09 Jun 2021 15:48:57

SAEID	USA-US115-2021-MRNA-1273-P301000017
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	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	09/APR/2021 06:19
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

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form (4)

Data signed: (b) (4) 16 Apr 2021 19:10:42

Generated On: 09 Jun 2021 15:48:57

SAEID	USA-US115-2021-MRNA-1273-P301000017
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	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/APR/2021 15:51
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

US3212181 (Prod: DM Clinical Research - ERN - PPDS)

US3212181

Form: Participant Creation

Generated On: 09 Jun 2021 15:48:57

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'US3212181'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 18:01:02

US3212181

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 18:01:56

US3212181

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 18:01:02

US3212181

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4)	14 Aug 2020 18:01:56

US3212181

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User entered 'SCRN'	System	14 Aug 2020 18:01:56

US3212181

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:48:57

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered (b) (6) 1962'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 18:01:03

US3212181

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:48:57

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '57'	Afifah Ayub (b) (4)	14 Aug 2020 18:03:51

US3212181

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:48:57

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User entered 'YEARS'	System	14 Aug 2020 18:03:51

US3212181

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:48:57

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User entered '57'	System	14 Aug 2020 18:04:03

US3212181

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:48:57

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Male (M)'	Afifah Ayub (b) (4)	14 Aug 2020 18:03:51

US3212181

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:48:57

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Afifah Ayub (b) (4)	14 Aug 2020 18:03:51

US3212181

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:48:57

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'I'	Afifah Ayub (b) (4)	14 Aug 2020 18:03:51

US3212181

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:48:57

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:03:51

US3212181

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:48:57

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:03:51

US3212181

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:48:57

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:03:51

US3212181

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:48:57

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:03:51

US3212181

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:48:57

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:03:51

US3212181

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:48:57

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 18:03:51

US3212181

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:48:57

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:03:51

US3212181

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:48:57

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:03:51

US3212181

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:48:57

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '14 Aug 2020'	Afifah Ayub (b) (4)	14 Aug 2020 18:04:03

US3212181

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User entered 'Aug 2020'	System	14 Aug 2020 18:04:03

US3212181

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User entered '2020'	System	14 Aug 2020 18:04:03

US3212181

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:48:57

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Amendment 2 (2)'	Afifah Ayub (b) (4)	14 Aug 2020 18:04:03

US3212181

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 18:04:03

US3212181

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 18:04:03

US3212181

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:48:57

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 18:04:03

US3212181

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:48:57

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:04:03

US3212181

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:48:57

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 18:01:02

US3212181

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:48:57

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User entered 'I'	System	14 Aug 2020 18:04:15

US3212181

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 18:04:15

US3212181

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:48:57

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	23 Mar 2021 18:59:07
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:04:38

US3212181

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:48:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 19:01:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 19:01:41
Data point term sent to Coder	System	23 Mar 2021 19:00:54
User entered 'Depression'	Laura Ngansop Djampou (b) (4)	23 Mar 2021 18:59:55

US3212181

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'un Feb 2016'	Laura Ngansop Djampou (b) (4)	23 Mar 2021 18:59:55

US3212181

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:48:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '0'	Laura Ngansop Djampou (b) (4)	23 Mar 2021 18:59:55

US3212181

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:48:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	23 Mar 2021 18:59:55

US3212181

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:48:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'un Sep 2016'	Laura Ngansop Djampou (b) (4)	23 Mar 2021 18:59:55

US3212181

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:48:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '0'	Laura Ngansop Djampou (b) (4)	23 Mar 2021 18:59:55

US3212181

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:48:57

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User entered 'Feb 2016'	System	23 Mar 2021 18:59:55

US3212181

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:48:57

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User entered '2016'	System	23 Mar 2021 18:59:55

US3212181

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:48:57

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User entered 'Sep 2016'	System	23 Mar 2021 18:59:55

US3212181

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:48:57

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User entered '2016'	System	23 Mar 2021 18:59:55

US3212181

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 18:05:22

US3212181

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '14 Aug 2020'	Afifah Ayub (b) (4)	14 Aug 2020 18:05:22

US3212181

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '11:54'	Afifah Ayub (b) (4)	14 Aug 2020 18:05:22

US3212181

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User entered '14 Aug 2020 11:54'	System	14 Aug 2020 18:05:22

US3212181

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '74' in	Afifah Ayub (b) (4)	14 Aug 2020 18:05:22
DataPoint set to visible.	(b) (4) System	14 Aug 2020 18:04:15

US3212181

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '175.8' lb	Afifah Ayub (b) (4)	14 Aug 2020 18:05:22
DataPoint set to visible.	(b) (4) System	14 Aug 2020 18:04:15

US3212181

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
Amendment Manager: User entered '22.61858'	System	16 Sep 2020 23:57:37
User entered '22.6'	System	14 Aug 2020 18:05:22
DataPoint set to visible.	System	14 Aug 2020 18:04:15

US3212181

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User entered 'kg/m2'	System	14 Aug 2020 18:05:22
DataPoint set to visible.	System	14 Aug 2020 18:04:15

US3212181

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Aug 2020 18:05:22

US3212181

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 18:41:01
Query 'Per CDM: Route of Measurement is recorded as 'Other' yet, 'If Other, Specify' has been recorded as "Not Done"? Please review and update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 16:43:56
User opened query 'Per CDM: Route of Measurement is recorded as 'Other' yet, 'If Other, Specify' has been recorded as "Not Done"? Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 16:41:11
User entered 'Other (Other)'	Afifah Ayub (b) (4)	14 Aug 2020 18:05:22

US3212181

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 18:41:01
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Aug 2020 18:05:22

US3212181

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Aug 2020 18:05:22

US3212181

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User entered 'bpm'	System	14 Aug 2020 18:05:22

US3212181

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Aug 2020 18:05:22

US3212181

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User entered 'breaths/min'	System	14 Aug 2020 18:05:22

US3212181

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Aug 2020 18:05:22

US3212181

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User entered 'mmHg'	System	14 Aug 2020 18:05:22

US3212181

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Aug 2020 18:05:22

US3212181

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User entered 'mmHg'	System	14 Aug 2020 18:05:22

US3212181

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30

US3212181

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30

US3212181

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:48:57

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 18:05:31

US3212181

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:48:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '14 Aug 2020'	Afifah Ayub (b) (4)	14 Aug 2020 18:05:31

US3212181

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:06:24

US3212181

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:06:24

US3212181

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:06:24

US3212181

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:06:24

US3212181

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:06:24

US3212181

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:06:24

US3212181

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:06:24

US3212181

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 18:06:24

US3212181

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:06:24

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:06:24

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:06:24

US3212181

Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 18:06:24

US3212181

Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Oil and gas consultant'	Afifah Ayub (b) (4)	14 Aug 2020 18:06:24

US3212181

Folder: Screening

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:06:24

US3212181

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:48:57

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:06:24

US3212181

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:06:24

US3212181

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:06:24

US3212181

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:06:24

US3212181

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '0'	Afifah Ayub (b) (4)	14 Aug 2020 18:06:24

US3212181

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:48:57

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'I'	Afifah Ayub (b) (4)	14 Aug 2020 18:06:24

US3212181

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:48:57

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:51:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Participant interacts with 5 or more people in person during the course of a typical workday. Participant attended large group events in the past few weeks (e.g., wedding, places of worship, concert).'	Afifah Ayub (b) (4)	14 Aug 2020 18:06:24

US3212181

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 18:06:41

US3212181

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '14 Aug 2020'	Afifah Ayub (b) (4)	14 Aug 2020 18:06:41

US3212181

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

[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 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4)	14 Aug 2020 18:06:41

US3212181

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered 'VISIT1'	System	14 Aug 2020 18:06:41

US3212181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 18:39:34

US3212181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:48:57

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:37:14
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:37:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 18:39:34
User entered '104356' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 18:39:34

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 18:39:34

US3212181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:48:57

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)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:40:47

US3212181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:48:57

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)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:40:47

US3212181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:40:47

US3212181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:48:57

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:40:47

US3212181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:48:57

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:40:47

US3212181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:48:57

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Afifah Ayub (b) (4)	05 Oct 2020 15:20:13
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:21:16
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:21:08

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:48:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:48:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:48:57

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:48:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User accepted default value 'Pre-Dose (PREDOSE)'	Afifah Ayub (b) (4) (b) (4)	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '14 Aug 2020'	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '11:54'	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered '14 Aug 2020 11:54'	System	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User closed query 'Per CDM: Please update 'Temperature' as per the required format (xxx.x).' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 18:18:14
Query 'Per CDM: Please update 'Temperature' as per the required format (xxx.x).' answered with 'updated' (Site from DM).	Heather Leary (b) (4)	09 Dec 2020 16:08:35
User entered '97.0' F reason for change: Data Entry Error	Heather Leary (b) (4)	09 Dec 2020 16:08:30
User opened query 'Per CDM: Please update 'Temperature' as per the required format (xxx.x).' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 15:03:35
User entered '97' F	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '78'	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered 'bpm'	System	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '15'	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered 'breaths/min'	System	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '140'	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered 'mmHg'	System	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '81'	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered 'mmHg'	System	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:48:57

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:48:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User accepted default value 'Post-Dose (POSTDOSE)'	Afifah Ayub (b) (4) (b) (4)	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '14 Aug 2020'	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 10:32:38
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'As per protocol, post-dose vitals are done at 30 minutes.' (Site from System).	Afifah Ayub (b) (4)	14 Aug 2020 20:50:11
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		14 Aug 2020 20:50:02
User entered '15:47'	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered '14 Aug 2020 15:47'	System	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User closed query 'Per CDM: Please Indicate CS or NCS' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 12:45:56
Query 'Per CDM: Please Indicate CS or NCS' answered with 'ncs' (Site from DM).	Afifah Ayub (b) (4)	14 Oct 2020 17:27:18
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 13:19:32
User opened query 'Per CDM: Please Indicate CS or NCS' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 13:19:29
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with '	(b) (4), (b) (6)	25 Sep 2020 19:14:32
Entered correctly - discussed with Investigator regarding low temperature reading' (Site from System).		
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:57:37
User entered '96.4' F	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '79'	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered 'bpm'	System	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '15'	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered 'breaths/min'	System	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '143'	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered 'mmHg'	System	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '79'	Afifah Ayub (b) (4)	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered 'mmHg'	System	14 Aug 2020 20:50:02

US3212181

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:48:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	15 Aug 2020 18:48:31
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	14 Aug 2020 18:41:00
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 18:41:00

US3212181

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:48:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	15 Aug 2020 18:48:31
User entered '14 Aug 2020'	Afifah Ayub (b) (4)	14 Aug 2020 18:41:00

US3212181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 19:58:26

US3212181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 19:58:26

US3212181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	14 Aug 2020 19:58:26

US3212181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 19:58:26

US3212181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '14 Aug 2020'	Afifah Ayub (b) (4)	14 Aug 2020 19:58:26

US3212181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '14:56'	Afifah Ayub (b) (4)	14 Aug 2020 19:58:26

US3212181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered '14 Aug 2020 14:56'	System	14 Aug 2020 19:58:26

US3212181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Left Arm (LEFT ARM)'	Afifah Ayub (b) (4)	14 Aug 2020 19:58:26

US3212181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered 'ONCE'	System	14 Aug 2020 19:58:26

US3212181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 19:58:26

US3212181

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 18:41:15

US3212181

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '14 Aug 2020'	Afifah Ayub (b) (4)	14 Aug 2020 18:41:15

US3212181

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '12:45'	Afifah Ayub (b) (4)	14 Aug 2020 18:41:15

US3212181

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered '14 Aug 2020 12:45'	System	14 Aug 2020 18:41:15

US3212181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:48:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User closed query 'Per GCL Lab Reconciliation: Swab: Per response, "subject had an unscheduled visit on 18SEP2020. We shipped his v1 PCR, but never received a report and reason for repeat PCR SWAB."; however, swab sample for 18-SEP-2020 is missing in EDC & per Preclarus, it is present under unscheduled visit accessioned as # 1F600117922, requisition ID # 1F605176038. Kindly consider initiating separate Covid-19 Assessment eCRF for 18-SEP-2020 and update swab data in COVID Diagnostic Test eCRF, irrespective of test result, else clarify.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 14:29:06
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Query 'Per GCL Lab Reconciliation: Swab: Per response, "subject had an unscheduled visit on 18SEP2020. We shipped his v1 PCR, but never received a report and reason for repeat PCR SWAB."; however, swab sample for 18-SEP-2020 is missing in EDC & per Preclarus, it is present under unscheduled visit accessioned as # 1F600117922, requisition ID # 1F605176038. Kindly consider initiating separate Covid-19 Assessment eCRF for 18-SEP-2020 and update swab data in COVID Diagnostic Test eCRF, irrespective of test result, else clarify.' answered with 'entered' (Site from DM).	Reagan Reed (b) (4)	01 Apr 2021 13:54:39
User opened query 'Per GCL Lab Reconciliation: Swab: Per response, "subject had an unscheduled visit on 18SEP2020. We shipped his v1 PCR, but never received a report and reason for repeat PCR SWAB."; however, swab sample for 18-SEP-2020 is missing in EDC & per Preclarus, it is present under unscheduled visit accessioned as # 1F600117922, requisition ID # 1F605176038. Kindly consider initiating separate Covid-19 Assessment eCRF for 18-SEP-2020 and update swab data in COVID Diagnostic Test eCRF, irrespective of test result, else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 10:36:46

US3212181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:48:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 18SEP2020 is reported underUnscheduled in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 12:08:26
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 18SEP2020 is reported underUnscheduled in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'subject had an unscheduled visit on 18SEp2020. We shipped his v1 PCR, but never received a report and reason for repeat PCR SWAB.' (Site from DM).	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 15:19:17
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 18SEP2020 is reported underUnscheduled in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 05:54:00
User entered '14 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	14 Aug 2020 18:41:31

US3212181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:48:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Afifah Ayub (b) (4) (b) (4)	14 Aug 2020 18:41:31

US3212181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:48:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 18:41:31

US3212181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:48:57

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '12:40'	Afifah Ayub (b) (4)	14 Aug 2020 18:41:31

US3212181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered '14 Aug 2020 12:40'	System	14 Aug 2020 18:41:31

US3212181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:48:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Afifah Ayub (b) (4) (b) (4)	14 Aug 2020 18:41:31

US3212181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:48:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Aug 2020 21:10:20
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Aug 2020 18:41:31

US3212181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:48:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Aug 2020 21:10:20
User entered '12:40'	Afifah Ayub (b) (4)	14 Aug 2020 18:41:31

US3212181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered empty.	System	25 Aug 2020 21:10:20
User entered '14 Aug 2020 12:40'	System	14 Aug 2020 18:41:31

US3212181

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	18 Aug 2020 20:41:51

US3212181

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered 'I'	System	18 Aug 2020 20:41:51

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T15:42:20', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '27dca799-a8f3-4a59-824c-109a1866419b' User entered 'Yes (Y)'	System	14 Aug 2020 20:42:46
	System	14 Aug 2020 20:42:46

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T15:42:31', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '27dca799-a8f3-4a59-824c-109a1866419b' User entered '96.4'	System	14 Aug 2020 20:42:46
	System	14 Aug 2020 20:42:46

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T15:42:36', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '27dca799-a8f3-4a59-824c-109a1866419b' User entered 'No (N)'	System	14 Aug 2020 20:42:46
	System	14 Aug 2020 20:42:46

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T15:42:45', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '27dca799-a8f3-4a59-824c-109a1866419b' User entered '14 Aug 2020 15:42'	System	14 Aug 2020 20:42:46
	System	14 Aug 2020 20:42:46

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '14 Aug 2020 15:16'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '14 Aug 2020 17:46'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T18:47:18', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0a583c0c-749a-4100-836e-1fe02e2e2433' User entered 'Yes (Y)'	System	14 Aug 2020 23:47:47
	System	14 Aug 2020 23:47:47

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T18:47:26', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0a583c0c-749a-4100-836e-1fe02e2e2433' User entered '97.3'	System	14 Aug 2020 23:47:47
	System	14 Aug 2020 23:47:47

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T18:47:32', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0a583c0c-749a-4100-836e-1fe02e2e2433'	System	14 Aug 2020 23:47:47
User entered 'No (N)'	System	14 Aug 2020 23:47:47

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T18:47:45', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0a583c0c-749a-4100-836e-1fe02e2e2433' User entered '14 Aug 2020 18:47'	System	14 Aug 2020 23:47:47
	System	14 Aug 2020 23:47:47

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '14 Aug 2020 18:41'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 2'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:48:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-15T19:25:02', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'e9612495-eb15-44e4-af03-70bf2b3eb32d'	System	16 Aug 2020 00:25:25
User entered 'Yes (Y)'	System	16 Aug 2020 00:25:25

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:48:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-15T19:25:09', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'e9612495-eb15-44e4-af03-70bf2b3eb32d' User entered '97.1'	System	16 Aug 2020 00:25:25
	System	16 Aug 2020 00:25:25

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-15T19:25:16', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'e9612495-eb15-44e4-af03-70bf2b3eb32d'	System	16 Aug 2020 00:25:25
User entered 'No (N)'	System	16 Aug 2020 00:25:25

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-15T19:25:22', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'e9612495-eb15-44e4-af03-70bf2b3eb32d'	System	16 Aug 2020 00:25:25
User entered '15 Aug 2020 19:25'	System	16 Aug 2020 00:25:25

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 3'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:48:57

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-16T18:49:26', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '2838844f-c966-48ea-9620-36704ff8b569' User entered 'Yes (Y)'	System	16 Aug 2020 23:49:46
	System	16 Aug 2020 23:49:46

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:48:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-16T18:49:36', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '2838844f-c966-48ea-9620-36704ff8b569' User entered '97.0'	System	16 Aug 2020 23:49:46
	System	16 Aug 2020 23:49:46

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-16T18:49:39', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '2838844f-c966-48ea-9620-36704ff8b569'	System	16 Aug 2020 23:49:46
User entered 'No (N)'	System	16 Aug 2020 23:49:46

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-16T18:49:44', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '2838844f-c966-48ea-9620-36704ff8b569' User entered '16 Aug 2020 18:49'	System	16 Aug 2020 23:49:46
	System	16 Aug 2020 23:49:46

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 4'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:48:57

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-17T18:08:20', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0413685d-510a-4d13-9a57-5a5bf73db8dd' User entered 'Yes (Y)'	System	17 Aug 2020 23:08:52
	System	17 Aug 2020 23:08:52

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:48:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-17T18:08:43', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0413685d-510a-4d13-9a57-5a5bf73db8dd' User entered '96.8'	System	17 Aug 2020 23:08:52
	System	17 Aug 2020 23:08:52

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-17T18:08:47', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0413685d-510a-4d13-9a57-5a5bf73db8dd'	System	17 Aug 2020 23:08:52
User entered 'No (N)'	System	17 Aug 2020 23:08:52

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-17T18:08:51', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0413685d-510a-4d13-9a57-5a5bf73db8dd' User entered '17 Aug 2020 18:08'	System	17 Aug 2020 23:08:52
	System	17 Aug 2020 23:08:52

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 5'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:48:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-18T18:04:25', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '79dbde53-d3a1-47ea-ae4b-2989b40ffffb' User entered 'Yes (Y)'	System	18 Aug 2020 23:04:44
	System	18 Aug 2020 23:04:44

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:48:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-18T18:04:32', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '79dbde53-d3a1-47ea-ae4b-2989b40ffffb' User entered '97.4'	System	18 Aug 2020 23:04:44
	System	18 Aug 2020 23:04:44

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-18T18:04:35', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '79dbde53-d3a1-47ea-ae4b-2989b40ffffb'	System	18 Aug 2020 23:04:44
User entered 'No (N)'	System	18 Aug 2020 23:04:44

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-18T18:04:42', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '79dbde53-d3a1-47ea-ae4b-2989b40ffffb' User entered '18 Aug 2020 18:04'	System	18 Aug 2020 23:04:44
	System	18 Aug 2020 23:04:44

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 6'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:48:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-19T21:31:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '16241f7c-cf51-4b6d-b800-acda4bd8c81e' User entered 'Yes (Y)'	System	20 Aug 2020 02:31:20
	System	20 Aug 2020 02:31:20

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:48:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-19T21:31:07', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '16241f7c-cf51-4b6d-b800-acda4bd8c81e' User entered '96.3'	System	20 Aug 2020 02:31:20
	System	20 Aug 2020 02:31:20

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-19T21:31:11', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '16241f7c-cf51-4b6d-b800-acda4bd8c81e' User entered 'No (N)'	System	20 Aug 2020 02:31:20
	System	20 Aug 2020 02:31:20

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-19T21:31:19', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '16241f7c-cf51-4b6d-b800-acda4bd8c81e' User entered '19 Aug 2020 21:31'	System	20 Aug 2020 02:31:20
	System	20 Aug 2020 02:31:20

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 7'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:48:57

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-20T18:38:03', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '08f3ddef-929b-40a1-b83e-23709513be1f' User entered 'Yes (Y)'	System	20 Aug 2020 23:38:28
	System	20 Aug 2020 23:38:28

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:48:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-20T18:38:16', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '08f3ddef-929b-40a1-b83e-23709513be1f' User entered '95.6'	System	20 Aug 2020 23:38:28
	System	20 Aug 2020 23:38:28

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-20T18:38:20', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '08f3ddef-929b-40a1-b83e-23709513be1f' User entered 'No (N)'	System	20 Aug 2020 23:38:28
	System	20 Aug 2020 23:38:28

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-20T18:38:24', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '08f3ddef-929b-40a1-b83e-23709513be1f' User entered '20 Aug 2020 18:38'	System	20 Aug 2020 23:38:28
	System	20 Aug 2020 23:38:28

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T15:43:17', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f195a9e1-fbdc-4d43-af2c-038bdb017d33'	System	14 Aug 2020 20:43:58
User entered 'None (1)'	System	14 Aug 2020 20:43:58

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T15:43:39', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f195a9e1-fbdc-4d43-af2c-038bdb017d33'	System	14 Aug 2020 20:43:58
User entered 'No (N)'	System	14 Aug 2020 20:43:58

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T15:43:43', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f195a9e1-fbdc-4d43-af2c-038bdb017d33'	System	14 Aug 2020 20:43:58
User entered 'No (N)'	System	14 Aug 2020 20:43:58

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T15:43:52', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f195a9e1-fbdc-4d43-af2c-038bdb017d33'	System	14 Aug 2020 20:43:58
User entered 'None (1)'	System	14 Aug 2020 20:43:58

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T15:43:57', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f195a9e1-fbdc-4d43-af2c-038bdb017d33'	System	14 Aug 2020 20:43:58
User entered '14 Aug 2020 15:43'	System	14 Aug 2020 20:43:58

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '14 Aug 2020 15:16'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '14 Aug 2020 17:46'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T18:45:14', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'aa22c79b-9ccc-474b-bacf-47efbaead025'	System	14 Aug 2020 23:45:38
User entered 'None (1)'	System	14 Aug 2020 23:45:38

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T18:45:18', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'aa22c79b-9ccc-474b-bacf-47efbaead025'	System	14 Aug 2020 23:45:38
User entered 'No (N)'	System	14 Aug 2020 23:45:38

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T18:45:22', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'aa22c79b-9ccc-474b-bacf-47efbaead025'	System	14 Aug 2020 23:45:38
User entered 'No (N)'	System	14 Aug 2020 23:45:38

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T18:45:31', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'aa22c79b-9ccc-474b-bacf-47efbaead025'	System	14 Aug 2020 23:45:38
User entered 'None (1)'	System	14 Aug 2020 23:45:38

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T18:45:37', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'aa22c79b-9ccc-474b-bacf-47efbaead025'	System	14 Aug 2020 23:45:38
User entered '14 Aug 2020 18:45'	System	14 Aug 2020 23:45:38

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '14 Aug 2020 18:41'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 2'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-15T19:25:36', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'b7d0807d-105b-44c0-aa42-e32dc9c75a41' User entered 'None (1)'	System	16 Aug 2020 00:26:16
	System	16 Aug 2020 00:26:16

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:48:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-15T19:25:40', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'b7d0807d-105b-44c0-aa42-e32dc9c75a41' User entered 'No (N)'	System	16 Aug 2020 00:26:16
	System	16 Aug 2020 00:26:16

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-15T19:25:58', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'b7d0807d-105b-44c0-aa42-e32dc9c75a41'	System	16 Aug 2020 00:26:16
User entered 'No (N)'	System	16 Aug 2020 00:26:16

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-15T19:26:08', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'b7d0807d-105b-44c0-aa42-e32dc9c75a41'	System	16 Aug 2020 00:26:16
User entered 'None (1)'	System	16 Aug 2020 00:26:16

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-15T19:26:15', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'b7d0807d-105b-44c0-aa42-e32dc9c75a41'	System	16 Aug 2020 00:26:16
User entered '15 Aug 2020 19:26'	System	16 Aug 2020 00:26:16

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 3'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-16T18:49:58', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f2ded7f0-8f4e-4f76-b187-c8e139c72451' User entered 'None (1)'	System	16 Aug 2020 23:50:30
	System	16 Aug 2020 23:50:30

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:48:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-16T18:50:08', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f2ded7f0-8f4e-4f76-b187-c8e139c72451'	System	16 Aug 2020 23:50:30
User entered 'No (N)'	System	16 Aug 2020 23:50:30

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-16T18:50:14', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f2ded7f0-8f4e-4f76-b187-c8e139c72451'	System	16 Aug 2020 23:50:30
User entered 'No (N)'	System	16 Aug 2020 23:50:30

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-16T18:50:23', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f2ded7f0-8f4e-4f76-b187-c8e139c72451' User entered 'None (1)'	System	16 Aug 2020 23:50:30
	System	16 Aug 2020 23:50:30

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-16T18:50:27', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f2ded7f0-8f4e-4f76-b187-c8e139c72451'	System	16 Aug 2020 23:50:30
User entered '16 Aug 2020 18:50'	System	16 Aug 2020 23:50:30

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 4'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-17T18:08:58', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'bd0ef854-9026-4a1f-8e7d-2d8ca75ae021' User entered 'None (1)'	System	17 Aug 2020 23:09:20
	System	17 Aug 2020 23:09:20

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:48:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-17T18:09:03', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'bd0ef854-9026-4a1f-8e7d-2d8ca75ae021' User entered 'No (N)'	System	17 Aug 2020 23:09:20
	System	17 Aug 2020 23:09:20

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-17T18:09:08', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'bd0ef854-9026-4a1f-8e7d-2d8ca75ae021' User entered 'No (N)'	System	17 Aug 2020 23:09:20
	System	17 Aug 2020 23:09:20

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-17T18:09:15', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'bd0ef854-9026-4a1f-8e7d-2d8ca75ae021' User entered 'None (1)'	System	17 Aug 2020 23:09:20
	System	17 Aug 2020 23:09:20

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-17T18:09:17', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'bd0ef854-9026-4a1f-8e7d-2d8ca75ae021' User entered '17 Aug 2020 18:09'	System	17 Aug 2020 23:09:20
	System	17 Aug 2020 23:09:20

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 5'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-18T18:03:24', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '989e80e6-b5a0-4a68-8e2c-922f91595827' User entered 'None (1)'	System	18 Aug 2020 23:03:47
	System	18 Aug 2020 23:03:47

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:48:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-18T18:03:29', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '989e80e6-b5a0-4a68-8e2c-922f91595827' User entered 'No (N)'	System	18 Aug 2020 23:03:47
	System	18 Aug 2020 23:03:47

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-18T18:03:32', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '989e80e6-b5a0-4a68-8e2c-922f91595827' User entered 'No (N)'	System	18 Aug 2020 23:03:47
	System	18 Aug 2020 23:03:47

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-18T18:03:40', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '989e80e6-b5a0-4a68-8e2c-922f91595827' User entered 'None (1)'	System	18 Aug 2020 23:03:47
	System	18 Aug 2020 23:03:47

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-18T18:03:44', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '989e80e6-b5a0-4a68-8e2c-922f91595827' User entered '18 Aug 2020 18:03'	System	18 Aug 2020 23:03:47
	System	18 Aug 2020 23:03:47

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 6'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-19T21:30:31', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '06c6d93e-f15a-4dfc-a837-7686866cab29'	System	20 Aug 2020 02:30:49
User entered 'None (1)'	System	20 Aug 2020 02:30:49

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:48:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-19T21:30:37', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '06c6d93e-f15a-4dfc-a837-7686866cab29' User entered 'No (N)'	System	20 Aug 2020 02:30:49
	System	20 Aug 2020 02:30:49

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-19T21:30:40', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '06c6d93e-f15a-4dfc-a837-7686866cab29' User entered 'No (N)'	System	20 Aug 2020 02:30:49
	System	20 Aug 2020 02:30:49

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-19T21:30:44', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '06c6d93e-f15a-4dfc-a837-7686866cab29' User entered 'None (1)'	System	20 Aug 2020 02:30:49
	System	20 Aug 2020 02:30:49

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-19T21:30:48', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '06c6d93e-f15a-4dfc-a837-7686866cab29' User entered '19 Aug 2020 21:30'	System	20 Aug 2020 02:30:49
	System	20 Aug 2020 02:30:49

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 7'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-20T18:37:40', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0cd49395-7b36-473f-a95a-c0e578c5bb8a' User entered 'None (1)'	System	20 Aug 2020 23:37:55
	System	20 Aug 2020 23:37:55

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:48:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-20T18:37:44', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0cd49395-7b36-473f-a95a-c0e578c5bb8a' User entered 'No (N)'	System	20 Aug 2020 23:37:55
	System	20 Aug 2020 23:37:55

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-20T18:37:46', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0cd49395-7b36-473f-a95a-c0e578c5bb8a' User entered 'No (N)'	System	20 Aug 2020 23:37:55
	System	20 Aug 2020 23:37:55

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-20T18:37:49', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0cd49395-7b36-473f-a95a-c0e578c5bb8a' User entered 'None (1)'	System	20 Aug 2020 23:37:55
	System	20 Aug 2020 23:37:55

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-20T18:37:52', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0cd49395-7b36-473f-a95a-c0e578c5bb8a' User entered '20 Aug 2020 18:37'	System	20 Aug 2020 23:37:55
	System	20 Aug 2020 23:37:55

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T15:44:03', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '32adb7d3-ed98-4aeb-830c-886b366a5584' User entered 'None (0)'	System	14 Aug 2020 20:44:29
	System	14 Aug 2020 20:44:29

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T15:44:06', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '32adb7d3-ed98-4aeb-830c-886b366a5584' User entered 'None (0)'	System	14 Aug 2020 20:44:29
	System	14 Aug 2020 20:44:29

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T15:44:10', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '32adb7d3-ed98-4aeb-830c-886b366a5584' User entered 'None (0)'	System	14 Aug 2020 20:44:29
	System	14 Aug 2020 20:44:29

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T15:44:14', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '32adb7d3-ed98-4aeb-830c-886b366a5584' User entered 'None (0)'	System	14 Aug 2020 20:44:29
	System	14 Aug 2020 20:44:29

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T15:44:17', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '32adb7d3-ed98-4aeb-830c-886b366a5584' User entered 'None (0)'	System	14 Aug 2020 20:44:29
	System	14 Aug 2020 20:44:29

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T15:44:19', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '32adb7d3-ed98-4aeb-830c-886b366a5584' User entered 'None (0)'	System	14 Aug 2020 20:44:29
	System	14 Aug 2020 20:44:29

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T15:44:23', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '32adb7d3-ed98-4aeb-830c-886b366a5584'	System	14 Aug 2020 20:44:29
User entered 'No (N)'	System	14 Aug 2020 20:44:29

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T15:44:26', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '32adb7d3-ed98-4aeb-830c-886b366a5584' User entered '14 Aug 2020 15:44'	System	14 Aug 2020 20:44:29
	System	14 Aug 2020 20:44:29

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '14 Aug 2020 15:16'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '14 Aug 2020 17:46'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T18:45:44', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '3b6b11cd-027c-49f9-bc90-beda27fdafe4' User entered 'None (0)'	System	14 Aug 2020 23:46:19
	System	14 Aug 2020 23:46:19

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T18:45:48', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '3b6b11cd-027c-49f9-bc90-beda27fdafe4' User entered 'None (0)'	System	14 Aug 2020 23:46:19
	System	14 Aug 2020 23:46:19

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T18:45:54', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '3b6b11cd-027c-49f9-bc90-beda27fdafe4' User entered 'None (0)'	System	14 Aug 2020 23:46:19
	System	14 Aug 2020 23:46:19

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T18:46:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '3b6b11cd-027c-49f9-bc90-beda27fdafe4' User entered 'None (0)'	System	14 Aug 2020 23:46:19
	System	14 Aug 2020 23:46:19

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T18:46:05', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '3b6b11cd-027c-49f9-bc90-beda27fdafe4' User entered 'None (0)'	System	14 Aug 2020 23:46:19
	System	14 Aug 2020 23:46:19

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T18:46:09', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '3b6b11cd-027c-49f9-bc90-beda27fdafe4' User entered 'None (0)'	System	14 Aug 2020 23:46:19
	System	14 Aug 2020 23:46:19

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T18:46:12', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '3b6b11cd-027c-49f9-bc90-beda27fdafe4'	System	14 Aug 2020 23:46:19
User entered 'No (N)'	System	14 Aug 2020 23:46:19

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-14T18:46:16', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '3b6b11cd-027c-49f9-bc90-beda27fdafe4' User entered '14 Aug 2020 18:46'	System	14 Aug 2020 23:46:19
	System	14 Aug 2020 23:46:19

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '14 Aug 2020 18:41'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 2'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-15T19:26:21', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd0fcca85-e804-4a4d-9a0b-2ba3d08672a8' User entered 'None (0)'	System	16 Aug 2020 00:27:16
	System	16 Aug 2020 00:27:16

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-15T19:26:24', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd0fcca85-e804-4a4d-9a0b-2ba3d08672a8' User entered 'None (0)'	System	16 Aug 2020 00:27:16
	System	16 Aug 2020 00:27:16

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-15T19:26:28', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd0fcca85-e804-4a4d-9a0b-2ba3d08672a8' User entered 'None (0)'	System	16 Aug 2020 00:27:16
	System	16 Aug 2020 00:27:16

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-15T19:26:31', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd0fcca85-e804-4a4d-9a0b-2ba3d08672a8' User entered 'None (0)'	System	16 Aug 2020 00:27:16
	System	16 Aug 2020 00:27:16

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-15T19:26:59', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd0fcca85-e804-4a4d-9a0b-2ba3d08672a8' User entered 'None (0)'	System	16 Aug 2020 00:27:16
	System	16 Aug 2020 00:27:16

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-15T19:27:02', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd0fcca85-e804-4a4d-9a0b-2ba3d08672a8' User entered 'None (0)'	System	16 Aug 2020 00:27:16
	System	16 Aug 2020 00:27:16

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-15T19:27:10', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd0fcca85-e804-4a4d-9a0b-2ba3d08672a8' User entered 'No (N)'	System	16 Aug 2020 00:27:16
	System	16 Aug 2020 00:27:16

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-15T19:27:14', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd0fcca85-e804-4a4d-9a0b-2ba3d08672a8' User entered '15 Aug 2020 19:27'	System	16 Aug 2020 00:27:16
	System	16 Aug 2020 00:27:16

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 3'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-16T18:50:33', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '9beac68c-c7d8-4280-b907-9bf4a0bc1a33' User entered 'None (0)'	System	16 Aug 2020 23:50:58
	System	16 Aug 2020 23:50:58

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-16T18:50:36', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '9beac68c-c7d8-4280-b907-9bf4a0bc1a33' User entered 'None (0)'	System	16 Aug 2020 23:50:58
	System	16 Aug 2020 23:50:58

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-16T18:50:40', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '9beac68c-c7d8-4280-b907-9bf4a0bc1a33' User entered 'None (0)'	System	16 Aug 2020 23:50:58
	System	16 Aug 2020 23:50:58

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-16T18:50:43', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '9beac68c-c7d8-4280-b907-9bf4a0bc1a33' User entered 'None (0)'	System	16 Aug 2020 23:50:58
	System	16 Aug 2020 23:50:58

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-16T18:50:46', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '9beac68c-c7d8-4280-b907-9bf4a0bc1a33' User entered 'None (0)'	System	16 Aug 2020 23:50:58
	System	16 Aug 2020 23:50:58

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-16T18:50:49', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '9beac68c-c7d8-4280-b907-9bf4a0bc1a33' User entered 'None (0)'	System	16 Aug 2020 23:50:58
	System	16 Aug 2020 23:50:58

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-16T18:50:52', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '9beac68c-c7d8-4280-b907-9bf4a0bc1a33' User entered 'No (N)'	System	16 Aug 2020 23:50:58
	System	16 Aug 2020 23:50:58

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-16T18:50:56', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '9beac68c-c7d8-4280-b907-9bf4a0bc1a33' User entered '16 Aug 2020 18:50'	System	16 Aug 2020 23:50:58
	System	16 Aug 2020 23:50:58

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 4'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-17T18:09:23', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0400f145-84e2-458d-beb9-299167b50e29' User entered 'None (0)'	System	17 Aug 2020 23:09:48
	System	17 Aug 2020 23:09:48

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-17T18:09:27', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0400f145-84e2-458d-beb9-299167b50e29' User entered 'None (0)'	System	17 Aug 2020 23:09:48
	System	17 Aug 2020 23:09:48

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-17T18:09:30', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0400f145-84e2-458d-beb9-299167b50e29' User entered 'None (0)'	System	17 Aug 2020 23:09:48
	System	17 Aug 2020 23:09:48

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-17T18:09:33', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0400f145-84e2-458d-beb9-299167b50e29' User entered 'None (0)'	System	17 Aug 2020 23:09:48
	System	17 Aug 2020 23:09:48

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-17T18:09:36', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0400f145-84e2-458d-beb9-299167b50e29' User entered 'None (0)'	System	17 Aug 2020 23:09:48
	System	17 Aug 2020 23:09:48

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-17T18:09:39', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0400f145-84e2-458d-beb9-299167b50e29' User entered 'None (0)'	System	17 Aug 2020 23:09:48
	System	17 Aug 2020 23:09:48

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-17T18:09:43', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0400f145-84e2-458d-beb9-299167b50e29' User entered 'No (N)'	System	17 Aug 2020 23:09:48
	System	17 Aug 2020 23:09:48

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-17T18:09:46', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0400f145-84e2-458d-beb9-299167b50e29' User entered '17 Aug 2020 18:09'	System	17 Aug 2020 23:09:48
	System	17 Aug 2020 23:09:48

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 5'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-18T18:03:50', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'c5f1c1ac-6a01-43e8-b224-5e229105c12e' User entered 'None (0)'	System	18 Aug 2020 23:04:20
	System	18 Aug 2020 23:04:20

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-18T18:03:53', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'c5f1c1ac-6a01-43e8-b224-5e229105c12e' User entered 'None (0)'	System	18 Aug 2020 23:04:20
	System	18 Aug 2020 23:04:20

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-18T18:03:56', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'c5f1c1ac-6a01-43e8-b224-5e229105c12e' User entered 'None (0)'	System	18 Aug 2020 23:04:20
	System	18 Aug 2020 23:04:20

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-18T18:03:59', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'c5f1c1ac-6a01-43e8-b224-5e229105c12e' User entered 'None (0)'	System	18 Aug 2020 23:04:20
	System	18 Aug 2020 23:04:20

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-18T18:04:02', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'c5f1c1ac-6a01-43e8-b224-5e229105c12e' User entered 'None (0)'	System	18 Aug 2020 23:04:20
	System	18 Aug 2020 23:04:20

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-18T18:04:10', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'c5f1c1ac-6a01-43e8-b224-5e229105c12e' User entered 'None (0)'	System	18 Aug 2020 23:04:20
	System	18 Aug 2020 23:04:20

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-18T18:04:13', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'c5f1c1ac-6a01-43e8-b224-5e229105c12e' User entered 'No (N)'	System	18 Aug 2020 23:04:20
	System	18 Aug 2020 23:04:20

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-18T18:04:18', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'c5f1c1ac-6a01-43e8-b224-5e229105c12e' User entered '18 Aug 2020 18:04'	System	18 Aug 2020 23:04:20
	System	18 Aug 2020 23:04:20

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 6'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-19T21:30:04', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '60973f6d-6c0e-486b-a6d3-79fe5781f1d5'	System	20 Aug 2020 02:30:28
User entered 'None (0)'	System	20 Aug 2020 02:30:28

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-19T21:30:07', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '60973f6d-6c0e-486b-a6d3-79fe5781f1d5'	System	20 Aug 2020 02:30:28
User entered 'None (0)'	System	20 Aug 2020 02:30:28

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-19T21:30:11', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '60973f6d-6c0e-486b-a6d3-79fe5781f1d5'	System	20 Aug 2020 02:30:28
User entered 'None (0)'	System	20 Aug 2020 02:30:28

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-19T21:30:13', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '60973f6d-6c0e-486b-a6d3-79fe5781f1d5'	System	20 Aug 2020 02:30:28
User entered 'None (0)'	System	20 Aug 2020 02:30:28

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-19T21:30:16', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '60973f6d-6c0e-486b-a6d3-79fe5781f1d5' User entered 'None (0)'	System	20 Aug 2020 02:30:28
	System	20 Aug 2020 02:30:28

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-19T21:30:19', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '60973f6d-6c0e-486b-a6d3-79fe5781f1d5'	System	20 Aug 2020 02:30:28
User entered 'None (0)'	System	20 Aug 2020 02:30:28

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-19T21:30:22', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '60973f6d-6c0e-486b-a6d3-79fe5781f1d5'	System	20 Aug 2020 02:30:28
User entered 'No (N)'	System	20 Aug 2020 02:30:28

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-19T21:30:26', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '60973f6d-6c0e-486b-a6d3-79fe5781f1d5'	System	20 Aug 2020 02:30:28
User entered '19 Aug 2020 21:30'	System	20 Aug 2020 02:30:28

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 7'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-20T18:37:19', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd09b2449-4a4a-45c6-8cef-1c871d6cac0a' User entered 'None (0)'	System	20 Aug 2020 23:37:42
	System	20 Aug 2020 23:37:42

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-20T18:37:22', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd09b2449-4a4a-45c6-8cef-1c871d6cac0a' User entered 'None (0)'	System	20 Aug 2020 23:37:42
	System	20 Aug 2020 23:37:42

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-20T18:37:24', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd09b2449-4a4a-45c6-8cef-1c871d6cac0a' User entered 'None (0)'	System	20 Aug 2020 23:37:42
	System	20 Aug 2020 23:37:42

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-20T18:37:26', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd09b2449-4a4a-45c6-8cef-1c871d6cac0a' User entered 'None (0)'	System	20 Aug 2020 23:37:42
	System	20 Aug 2020 23:37:42

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-20T18:37:28', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd09b2449-4a4a-45c6-8cef-1c871d6cac0a' User entered 'None (0)'	System	20 Aug 2020 23:37:42
	System	20 Aug 2020 23:37:42

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-20T18:37:30', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd09b2449-4a4a-45c6-8cef-1c871d6cac0a' User entered 'None (0)'	System	20 Aug 2020 23:37:42
	System	20 Aug 2020 23:37:42

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-20T18:37:33', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd09b2449-4a4a-45c6-8cef-1c871d6cac0a' User entered 'No (N)'	System	20 Aug 2020 23:37:42
	System	20 Aug 2020 23:37:42

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-08-20T18:37:36', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd09b2449-4a4a-45c6-8cef-1c871d6cac0a' User entered '20 Aug 2020 18:37'	System	20 Aug 2020 23:37:42
	System	20 Aug 2020 23:37:42

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 19:58:26

US3212181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Heather Leary (b) (4)	21 Aug 2020 21:10:52

US3212181

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '21 Aug 2020'	Heather Leary (b) (4)	21 Aug 2020 21:10:52

US3212181

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Contact Made (CONTACT MADE)'	Heather Leary (b) (4)	21 Aug 2020 21:10:52

US3212181

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Heather Leary (b) (4)	21 Aug 2020 21:10:52

US3212181

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Heather Leary (b) (4)	21 Aug 2020 21:10:56

US3212181

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered 'I'	System	21 Aug 2020 21:10:56

US3212181

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	31 Aug 2020 17:54:05

US3212181

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '29 Aug 2020'	Laura Ngansop Djampou (b) (4)	31 Aug 2020 17:54:05

US3212181

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	31 Aug 2020 17:54:05

US3212181

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou (b) (4)	31 Aug 2020 17:54:05

US3212181

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	31 Aug 2020 17:54:14

US3212181

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered 'I'	System	31 Aug 2020 17:54:14

US3212181

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Heather Leary (b) (4)	05 Sep 2020 16:28:55

US3212181

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '4 Sep 2020'	Heather Leary (b) (4)	05 Sep 2020 16:28:55

US3212181

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Contact Made (CONTACT MADE)'	Heather Leary (b) (4)	05 Sep 2020 16:28:55

US3212181

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Heather Leary (b) (4)	05 Sep 2020 16:28:55

US3212181

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 17:20:41

US3212181

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered 'I'	System	14 Sep 2020 17:20:41

US3212181

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:32:32

US3212181

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 09:24:04
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'confirmed' (Site from System).	Anna Pena (b) (4)	13 Oct 2020 20:10:59
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	02 Oct 2020 19:55:36
User entered '02 Oct 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	02 Oct 2020 19:55:36
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	02 Oct 2020 19:32:53
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered by data change (Site from System).	System	02 Oct 2020 19:32:53
User entered '18 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:32:53
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	02 Oct 2020 19:32:32
User entered '2 Oct 2020'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:32:32

US3212181

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

[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 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:32:32

US3212181

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'VISIT2'	System	02 Oct 2020 19:32:32

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User accepted default value 'Pre-Dose (PREDOSE)'	Laura Ngansop Djampou	02 Oct 2020 19:33:41
	(b) (4)	

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:33:41

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '02 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	14 Dec 2020 17:30:10
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Oct 2020 19:55:36
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Oct 2020 19:33:41
User entered '2 Oct 2020'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:33:41

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '11:45'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:33:41

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered '02 Oct 2020 11:45'	System	14 Dec 2020 17:30:10
User entered '2 Oct 2020 11:45'	System	02 Oct 2020 19:33:41

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '98.0' F	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:33:41

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:33:41

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:33:41

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '69'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:33:41

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'bpm'	System	02 Oct 2020 19:33:41

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '16'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:33:41

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'breaths/min'	System	02 Oct 2020 19:33:41

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '136'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:33:41

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'mmHg'	System	02 Oct 2020 19:33:41

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '92'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:33:41

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'mmHg'	System	02 Oct 2020 19:33:41

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User accepted default value 'Post-Dose (POSTDOSE)'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:34:34

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:34:34

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '02 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	14 Dec 2020 17:30:10
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Oct 2020 19:55:36
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Oct 2020 19:34:34
User entered '2 Oct 2020'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:34:34

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '14:17'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:34:34

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered '02 Oct 2020 14:17'	System	14 Dec 2020 17:30:10
User entered '2 Oct 2020 14:17'	System	02 Oct 2020 19:34:34

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '97.5' F	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:34:34

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:34:34

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:34:34

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '73'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:34:34

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'bpm'	System	02 Oct 2020 19:34:34

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '16'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:34:34

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'breaths/min'	System	02 Oct 2020 19:34:34

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '134'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:34:34

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'mmHg'	System	02 Oct 2020 19:34:34

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '80'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:34:34

US3212181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'mmHg'	System	02 Oct 2020 19:34:34

US3212181

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:48:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:34:43

US3212181

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:48:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '02 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	14 Dec 2020 17:30:16
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Oct 2020 19:55:36
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Oct 2020 19:34:43
User entered '2 Oct 2020'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:34:43

US3212181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	02 Oct 2020 19:18:29

US3212181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	02 Oct 2020 19:18:29

US3212181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	02 Oct 2020 19:18:29

US3212181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'MRNA-1273 OR PLACEBO'	System	02 Oct 2020 19:18:29

US3212181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User closed query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 20:46:08
Query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly, else clarify.' answered with 'deviation captured in source' (Site from DM).	Reagan Reed (b) (4)	18 Dec 2020 15:42:56
User opened query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 10:49:36
User entered '02 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	14 Dec 2020 17:30:28
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	02 Oct 2020 19:55:36
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	02 Oct 2020 19:55:36
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	02 Oct 2020 19:32:53
User entered '2 Oct 2020'	Afifah Ayub (b) (4)	02 Oct 2020 19:18:29

US3212181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '13:36'	Afifah Ayub (b) (4)	02 Oct 2020 19:18:29

US3212181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered '02 Oct 2020 13:36'	System	14 Dec 2020 17:30:28
User entered '2 Oct 2020 13:36'	System	02 Oct 2020 19:18:29

US3212181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Left Arm (LEFT ARM)'	Afifah Ayub (b) (4)	02 Oct 2020 19:18:29

US3212181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'ONCE'	System	02 Oct 2020 19:18:29

US3212181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'INTRAMUSCULAR'	System	02 Oct 2020 19:18:29

US3212181

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:35:04

US3212181

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '02 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	14 Dec 2020 17:29:53
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Oct 2020 19:55:36
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		02 Oct 2020 19:55:36
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Oct 2020 19:35:04
User entered '2 Oct 2020'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:35:04

US3212181

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '12:44'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:35:04

US3212181

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered '02 Oct 2020 12:44'	System	14 Dec 2020 17:29:53
User entered '2 Oct 2020 12:44'	System	02 Oct 2020 19:35:04

US3212181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:48:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '02 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	14 Dec 2020 17:30:36
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Oct 2020 19:55:36
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		02 Oct 2020 19:55:36
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Oct 2020 19:35:25
User entered '2 Oct 2020'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:35:25

US3212181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:48:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:35:25

US3212181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:48:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:35:25

US3212181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:48:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '12:39'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:35:25

US3212181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered '02 Oct 2020 12:39'	System	14 Dec 2020 17:30:36
User entered '2 Oct 2020 12:39'	System	02 Oct 2020 19:35:25

US3212181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:48:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:35:25

US3212181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:48:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:35:25

US3212181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:48:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:35:25

US3212181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered empty.	System	02 Oct 2020 19:35:25

US3212181

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	02 Oct 2020 19:35:35

US3212181

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered 'I'	System	02 Oct 2020 19:35:35

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	02 Oct 2020 19:18:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T14:18:43', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'e44073a6-6c46-44c3-acaf-436ddad199e5' User entered 'Yes (Y)'	System	02 Oct 2020 19:19:05
	System	02 Oct 2020 19:19:05

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T14:18:50', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'e44073a6-6c46-44c3-acaf-436ddad199e5' User entered '97.5'	System	02 Oct 2020 19:19:05
	System	02 Oct 2020 19:19:05

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T14:18:54', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'e44073a6-6c46-44c3-acaf-436ddad199e5'	System	02 Oct 2020 19:19:05
User entered 'No (N)'	System	02 Oct 2020 19:19:05

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T14:19:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'e44073a6-6c46-44c3-acaf-436ddad199e5' User entered '02 Oct 2020 14:19'	System	02 Oct 2020 19:19:05
	System	02 Oct 2020 19:19:05

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '02 Oct 2020 13:56'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '02 Oct 2020 16:26'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	02 Oct 2020 19:18:29
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T17:29:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0ca6fcd4-e046-4fff-b6fa-3d24dc475301' User entered 'Yes (Y)'	System	02 Oct 2020 22:29:19
	System	02 Oct 2020 22:29:19

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T17:29:07', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0ca6fcd4-e046-4fff-b6fa-3d24dc475301' User entered '95.6'	System	02 Oct 2020 22:29:19
	System	02 Oct 2020 22:29:19

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T17:29:11', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0ca6fcd4-e046-4fff-b6fa-3d24dc475301'	System	02 Oct 2020 22:29:19
User entered 'No (N)'	System	02 Oct 2020 22:29:19

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T17:29:17', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0ca6fcd4-e046-4fff-b6fa-3d24dc475301' User entered '02 Oct 2020 17:29'	System	02 Oct 2020 22:29:19
	System	02 Oct 2020 22:29:19

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '02 Oct 2020 17:21'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	02 Oct 2020 19:18:29
User entered 'Day 2'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:48:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-04T09:36:49', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '93b1d7b2-85a5-42e0-8973-50c44a923c80' User entered 'Yes (Y)'	System	04 Oct 2020 14:37:19
	System	04 Oct 2020 14:37:19

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:48:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-04T09:36:56', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '93b1d7b2-85a5-42e0-8973-50c44a923c80' User entered '97.9'	System	04 Oct 2020 14:37:19
	System	04 Oct 2020 14:37:19

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-04T09:37:01', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '93b1d7b2-85a5-42e0-8973-50c44a923c80'	System	04 Oct 2020 14:37:19
User entered 'No (N)'	System	04 Oct 2020 14:37:19

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-04T09:37:16', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '93b1d7b2-85a5-42e0-8973-50c44a923c80' User entered '04 Oct 2020 09:37'	System	04 Oct 2020 14:37:19
	System	04 Oct 2020 14:37:19

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	02 Oct 2020 19:18:29
User entered 'Day 3'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:48:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-05T09:45:21', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'c992d81e-606d-42eb-be2c-2525650ec8a0' User entered 'Yes (Y)'	System	05 Oct 2020 14:45:43
	System	05 Oct 2020 14:45:43

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:48:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-05T09:45:29', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'c992d81e-606d-42eb-be2c-2525650ec8a0' User entered '98.2'	System	05 Oct 2020 14:45:43
	System	05 Oct 2020 14:45:43

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-05T09:45:34', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'c992d81e-606d-42eb-be2c-2525650ec8a0' User entered 'No (N)'	System	05 Oct 2020 14:45:43
	System	05 Oct 2020 14:45:43

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-05T09:45:39', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'c992d81e-606d-42eb-be2c-2525650ec8a0' User entered '05 Oct 2020 09:45'	System	05 Oct 2020 14:45:43
	System	05 Oct 2020 14:45:43

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	02 Oct 2020 19:18:29
User entered 'Day 4'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:48:57

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T09:07:35', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '844a0413-4fe1-458b-9a3c-e9a6ed4305eb' User entered 'Yes (Y)'	System	06 Oct 2020 14:07:54
	System	06 Oct 2020 14:07:54

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:48:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T09:07:44', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '844a0413-4fe1-458b-9a3c-e9a6ed4305eb' User entered '98.3'	System	06 Oct 2020 14:07:54
	System	06 Oct 2020 14:07:54

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T09:07:47', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '844a0413-4fe1-458b-9a3c-e9a6ed4305eb' User entered 'No (N)'	System	06 Oct 2020 14:07:54
	System	06 Oct 2020 14:07:54

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T09:07:50', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '844a0413-4fe1-458b-9a3c-e9a6ed4305eb' User entered '06 Oct 2020 09:07'	System	06 Oct 2020 14:07:54
	System	06 Oct 2020 14:07:54

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	02 Oct 2020 19:18:29
User entered 'Day 5'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:48:57

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T17:05:55', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'dcf1bc49-e904-4985-9720-ebad14b63132' User entered 'Yes (Y)'	System	06 Oct 2020 22:06:20
	System	06 Oct 2020 22:06:20

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:48:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T17:06:10', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'dcf1bc49-e904-4985-9720-ebad14b63132' User entered '97.6'	System	06 Oct 2020 22:06:20
	System	06 Oct 2020 22:06:20

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T17:06:14', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'dcf1bc49-e904-4985-9720-ebad14b63132'	System	06 Oct 2020 22:06:20
User entered 'No (N)'	System	06 Oct 2020 22:06:20

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T17:06:17', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'dcf1bc49-e904-4985-9720-ebad14b63132' User entered '06 Oct 2020 17:06'	System	06 Oct 2020 22:06:20
	System	06 Oct 2020 22:06:20

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	02 Oct 2020 19:18:29
User entered 'Day 6'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:48:57

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-07T12:02:09', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '3b649d92-c94e-408b-a4d7-762ee97794b4' User entered 'Yes (Y)'	System	07 Oct 2020 17:03:09
	System	07 Oct 2020 17:03:09

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:48:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-07T12:02:38', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '3b649d92-c94e-408b-a4d7-762ee97794b4' User entered '97.0'	System	07 Oct 2020 17:03:09
	System	07 Oct 2020 17:03:09

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-07T12:02:42', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '3b649d92-c94e-408b-a4d7-762ee97794b4'	System	07 Oct 2020 17:03:09
User entered 'No (N)'	System	07 Oct 2020 17:03:09

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-07T12:02:47', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '3b649d92-c94e-408b-a4d7-762ee97794b4' User entered '07 Oct 2020 12:02'	System	07 Oct 2020 17:03:09
	System	07 Oct 2020 17:03:09

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	02 Oct 2020 19:18:29
User entered 'Day 7'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:48:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-08T12:01:05', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'b64c67bd-2192-49d3-9654-30f4b9dd180e' User entered 'Yes (Y)'	System	08 Oct 2020 17:01:59
	System	08 Oct 2020 17:01:59

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:48:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-08T12:01:11', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'b64c67bd-2192-49d3-9654-30f4b9dd180e' User entered '97.5'	System	08 Oct 2020 17:01:59
	System	08 Oct 2020 17:01:59

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-08T12:01:14', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'b64c67bd-2192-49d3-9654-30f4b9dd180e' User entered 'No (N)'	System	08 Oct 2020 17:01:59
	System	08 Oct 2020 17:01:59

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-08T12:01:18', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'b64c67bd-2192-49d3-9654-30f4b9dd180e' User entered '08 Oct 2020 12:01'	System	08 Oct 2020 17:01:59
	System	08 Oct 2020 17:01:59

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	02 Oct 2020 19:18:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T14:19:05', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'de1cf6ad-d828-4904-bf3f-5ad5a23a9aea' User entered 'None (1)'	System	02 Oct 2020 19:19:23
	System	02 Oct 2020 19:19:23

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T14:19:09', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'de1cf6ad-d828-4904-bf3f-5ad5a23a9aea' User entered 'No (N)'	System	02 Oct 2020 19:19:23
	System	02 Oct 2020 19:19:23

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T14:19:11', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'de1cf6ad-d828-4904-bf3f-5ad5a23a9aea' User entered 'No (N)'	System	02 Oct 2020 19:19:23
	System	02 Oct 2020 19:19:23

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T14:19:16', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'de1cf6ad-d828-4904-bf3f-5ad5a23a9aea' User entered 'None (1)'	System	02 Oct 2020 19:19:23
	System	02 Oct 2020 19:19:23

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T14:19:19', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'de1cf6ad-d828-4904-bf3f-5ad5a23a9aea' User entered '02 Oct 2020 14:19'	System	02 Oct 2020 19:19:23
	System	02 Oct 2020 19:19:23

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '02 Oct 2020 13:56'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '02 Oct 2020 16:26'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	02 Oct 2020 19:18:29
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T17:27:51', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd5fd3701-95de-475d-93a3-72b2e34d2c39'	System	02 Oct 2020 22:28:18
User entered 'None (1)'	System	02 Oct 2020 22:28:18

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T17:27:56', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd5fd3701-95de-475d-93a3-72b2e34d2c39'	System	02 Oct 2020 22:28:18
User entered 'No (N)'	System	02 Oct 2020 22:28:18

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T17:28:02', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd5fd3701-95de-475d-93a3-72b2e34d2c39'	System	02 Oct 2020 22:28:18
User entered 'No (N)'	System	02 Oct 2020 22:28:18

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T17:28:06', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd5fd3701-95de-475d-93a3-72b2e34d2c39'	System	02 Oct 2020 22:28:18
User entered 'None (1)'	System	02 Oct 2020 22:28:18

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T17:28:15', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd5fd3701-95de-475d-93a3-72b2e34d2c39'	System	02 Oct 2020 22:28:18
User entered '02 Oct 2020 17:28'	System	02 Oct 2020 22:28:18

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '02 Oct 2020 17:21'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	02 Oct 2020 19:18:29
User entered 'Day 2'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-04T09:35:53', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'baa8186a-f106-45e4-8aca-158b13de16a2' User entered 'None (1)'	System	04 Oct 2020 14:36:08
	System	04 Oct 2020 14:36:08

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:48:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-04T09:35:56', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'baa8186a-f106-45e4-8aca-158b13de16a2' User entered 'No (N)'	System	04 Oct 2020 14:36:08
	System	04 Oct 2020 14:36:08

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-04T09:36:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'baa8186a-f106-45e4-8aca-158b13de16a2' User entered 'No (N)'	System	04 Oct 2020 14:36:08
	System	04 Oct 2020 14:36:08

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-04T09:36:03', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'baa8186a-f106-45e4-8aca-158b13de16a2' User entered 'None (1)'	System	04 Oct 2020 14:36:08
	System	04 Oct 2020 14:36:08

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-04T09:36:06', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'baa8186a-f106-45e4-8aca-158b13de16a2' User entered '04 Oct 2020 09:36'	System	04 Oct 2020 14:36:08
	System	04 Oct 2020 14:36:08

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	02 Oct 2020 19:18:29
User entered 'Day 3'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-05T09:44:10', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'be588774-6fde-4e08-be8f-adfd2e6d0ec7' User entered 'None (1)'	System	05 Oct 2020 14:44:26
	System	05 Oct 2020 14:44:26

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:48:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-05T09:44:14', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'be588774-6fde-4e08-be8f-adfd2e6d0ec7' User entered 'No (N)'	System	05 Oct 2020 14:44:26
	System	05 Oct 2020 14:44:26

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-05T09:44:17', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'be588774-6fde-4e08-be8f-adfd2e6d0ec7' User entered 'No (N)'	System	05 Oct 2020 14:44:26
	System	05 Oct 2020 14:44:26

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-05T09:44:20', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'be588774-6fde-4e08-be8f-adfd2e6d0ec7' User entered 'None (1)'	System	05 Oct 2020 14:44:26
	System	05 Oct 2020 14:44:26

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-05T09:44:24', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'be588774-6fde-4e08-be8f-adfd2e6d0ec7' User entered '05 Oct 2020 09:44'	System	05 Oct 2020 14:44:26
	System	05 Oct 2020 14:44:26

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	02 Oct 2020 19:18:29
User entered 'Day 4'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T09:07:11', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '62219b35-c98c-452d-96cd-ebf67da43865'	System	06 Oct 2020 14:07:32
User entered 'None (1)'	System	06 Oct 2020 14:07:32

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:48:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T09:07:20', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '62219b35-c98c-452d-96cd-ebf67da43865'	System	06 Oct 2020 14:07:32
User entered 'No (N)'	System	06 Oct 2020 14:07:32

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T09:07:24', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '62219b35-c98c-452d-96cd-ebf67da43865'	System	06 Oct 2020 14:07:32
User entered 'No (N)'	System	06 Oct 2020 14:07:32

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T09:07:26', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '62219b35-c98c-452d-96cd-ebf67da43865'	System	06 Oct 2020 14:07:32
User entered 'None (1)'	System	06 Oct 2020 14:07:32

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T09:07:29', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '62219b35-c98c-452d-96cd-ebf67da43865' User entered '06 Oct 2020 09:07'	System	06 Oct 2020 14:07:32
	System	06 Oct 2020 14:07:32

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	02 Oct 2020 19:18:29
User entered 'Day 5'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T17:06:30', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'c704c1ea-f13c-4504-aa09-3599062188d3'	System	06 Oct 2020 22:06:44
User entered 'None (1)'	System	06 Oct 2020 22:06:44

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:48:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T17:06:26', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'c704c1ea-f13c-4504-aa09-3599062188d3'	System	06 Oct 2020 22:06:44
User entered 'No (N)'	System	06 Oct 2020 22:06:44

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T17:06:33', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'c704c1ea-f13c-4504-aa09-3599062188d3' User entered 'No (N)'	System	06 Oct 2020 22:06:44
	System	06 Oct 2020 22:06:44

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T17:06:37', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'c704c1ea-f13c-4504-aa09-3599062188d3' User entered 'None (1)'	System	06 Oct 2020 22:06:44
	System	06 Oct 2020 22:06:44

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T17:06:42', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'c704c1ea-f13c-4504-aa09-3599062188d3' User entered '06 Oct 2020 17:06'	System	06 Oct 2020 22:06:44
	System	06 Oct 2020 22:06:44

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	02 Oct 2020 19:18:29
User entered 'Day 6'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-07T12:00:25', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'a2c082e9-36f5-49f9-ab2b-bfb40d844f31'	System	07 Oct 2020 17:00:50
User entered 'None (1)'	System	07 Oct 2020 17:00:50

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:48:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-07T12:00:30', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'a2c082e9-36f5-49f9-ab2b-bfb40d844f31' User entered 'No (N)'	System	07 Oct 2020 17:00:50
	System	07 Oct 2020 17:00:50

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-07T12:00:34', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'a2c082e9-36f5-49f9-ab2b-bfb40d844f31' User entered 'No (N)'	System	07 Oct 2020 17:00:50
	System	07 Oct 2020 17:00:50

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-07T12:00:36', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'a2c082e9-36f5-49f9-ab2b-bfb40d844f31' User entered 'None (1)'	System	07 Oct 2020 17:00:50
	System	07 Oct 2020 17:00:50

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-07T12:00:39', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'a2c082e9-36f5-49f9-ab2b-bfb40d844f31' User entered '07 Oct 2020 12:00'	System	07 Oct 2020 17:00:50
	System	07 Oct 2020 17:00:50

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	02 Oct 2020 19:18:29
User entered 'Day 7'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-08T12:01:31', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '30ceffeb-6845-48f2-8175-648f3c27d63a'	System	08 Oct 2020 17:02:32
User entered 'None (1)'	System	08 Oct 2020 17:02:32

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:48:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-08T12:01:34', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '30ceffeb-6845-48f2-8175-648f3c27d63a' User entered 'No (N)'	System	08 Oct 2020 17:02:32
	System	08 Oct 2020 17:02:32

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-08T12:01:38', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '30ceffeb-6845-48f2-8175-648f3c27d63a' User entered 'No (N)'	System	08 Oct 2020 17:02:32
	System	08 Oct 2020 17:02:32

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:48:57

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-08T12:01:41', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '30ceffeb-6845-48f2-8175-648f3c27d63a'	System	08 Oct 2020 17:02:32
User entered 'None (1)'	System	08 Oct 2020 17:02:32

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:48:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-08T12:01:46', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '30ceffeb-6845-48f2-8175-648f3c27d63a' User entered '08 Oct 2020 12:01'	System	08 Oct 2020 17:02:32
	System	08 Oct 2020 17:02:32

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	02 Oct 2020 19:18:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T14:19:23', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'a8b0e354-2ee5-4375-830c-f0ba30125813' User entered 'None (0)'	System	02 Oct 2020 19:19:44
	System	02 Oct 2020 19:19:44

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T14:19:25', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'a8b0e354-2ee5-4375-830c-f0ba30125813' User entered 'None (0)'	System	02 Oct 2020 19:19:44
	System	02 Oct 2020 19:19:44

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T14:19:28', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'a8b0e354-2ee5-4375-830c-f0ba30125813' User entered 'None (0)'	System	02 Oct 2020 19:19:44
	System	02 Oct 2020 19:19:44

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T14:19:30', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'a8b0e354-2ee5-4375-830c-f0ba30125813' User entered 'None (0)'	System	02 Oct 2020 19:19:44
	System	02 Oct 2020 19:19:44

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T14:19:32', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'a8b0e354-2ee5-4375-830c-f0ba30125813' User entered 'None (0)'	System	02 Oct 2020 19:19:44
	System	02 Oct 2020 19:19:44

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T14:19:34', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'a8b0e354-2ee5-4375-830c-f0ba30125813' User entered 'None (0)'	System	02 Oct 2020 19:19:44
	System	02 Oct 2020 19:19:44

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T14:19:38', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'a8b0e354-2ee5-4375-830c-f0ba30125813' User entered 'No (N)'	System	02 Oct 2020 19:19:44
	System	02 Oct 2020 19:19:44

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T14:19:41', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'a8b0e354-2ee5-4375-830c-f0ba30125813' User entered '02 Oct 2020 14:19'	System	02 Oct 2020 19:19:44
	System	02 Oct 2020 19:19:44

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '02 Oct 2020 13:56'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '02 Oct 2020 16:26'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	02 Oct 2020 19:18:29
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T17:28:21', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '8b63e3bb-71f4-4561-a593-e267490fcfab' User entered 'None (0)'	System	02 Oct 2020 22:28:44
	System	02 Oct 2020 22:28:44

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T17:28:24', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '8b63e3bb-71f4-4561-a593-e267490fcfab' User entered 'None (0)'	System	02 Oct 2020 22:28:44
	System	02 Oct 2020 22:28:44

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T17:28:27', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '8b63e3bb-71f4-4561-a593-e267490fcfab' User entered 'None (0)'	System	02 Oct 2020 22:28:44
	System	02 Oct 2020 22:28:44

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T17:28:30', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '8b63e3bb-71f4-4561-a593-e267490fcfab' User entered 'None (0)'	System	02 Oct 2020 22:28:44
	System	02 Oct 2020 22:28:44

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T17:28:32', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '8b63e3bb-71f4-4561-a593-e267490fcfab' User entered 'None (0)'	System	02 Oct 2020 22:28:44
	System	02 Oct 2020 22:28:44

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T17:28:35', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '8b63e3bb-71f4-4561-a593-e267490fcfab' User entered 'None (0)'	System	02 Oct 2020 22:28:44
	System	02 Oct 2020 22:28:44

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T17:28:39', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '8b63e3bb-71f4-4561-a593-e267490fcfab' User entered 'No (N)'	System	02 Oct 2020 22:28:44
	System	02 Oct 2020 22:28:44

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-02T17:28:43', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '8b63e3bb-71f4-4561-a593-e267490fcfab' User entered '02 Oct 2020 17:28'	System	02 Oct 2020 22:28:44
	System	02 Oct 2020 22:28:44

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '02 Oct 2020 17:21'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	02 Oct 2020 19:18:29
User entered 'Day 2'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-04T09:36:11', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'e7fddc8c-aaa9-4e06-a790-c0de804563c4' User entered 'None (0)'	System	04 Oct 2020 14:36:34
	System	04 Oct 2020 14:36:34

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-04T09:36:14', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'e7fddc8c-aaa9-4e06-a790-c0de804563c4' User entered 'None (0)'	System	04 Oct 2020 14:36:34
	System	04 Oct 2020 14:36:34

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-04T09:36:19', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'e7fddc8c-aaa9-4e06-a790-c0de804563c4' User entered 'None (0)'	System	04 Oct 2020 14:36:34
	System	04 Oct 2020 14:36:34

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-04T09:36:21', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'e7fddc8c-aaa9-4e06-a790-c0de804563c4' User entered 'None (0)'	System	04 Oct 2020 14:36:34
	System	04 Oct 2020 14:36:34

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-04T09:36:24', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'e7fddc8c-aaa9-4e06-a790-c0de804563c4' User entered 'None (0)'	System	04 Oct 2020 14:36:34
	System	04 Oct 2020 14:36:34

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-04T09:36:26', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'e7fddc8c-aaa9-4e06-a790-c0de804563c4' User entered 'None (0)'	System	04 Oct 2020 14:36:34
	System	04 Oct 2020 14:36:34

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-04T09:36:30', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'e7fddc8c-aaa9-4e06-a790-c0de804563c4' User entered 'No (N)'	System	04 Oct 2020 14:36:34
	System	04 Oct 2020 14:36:34

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-04T09:36:32', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'e7fddc8c-aaa9-4e06-a790-c0de804563c4' User entered '04 Oct 2020 09:36'	System	04 Oct 2020 14:36:34
	System	04 Oct 2020 14:36:34

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	02 Oct 2020 19:18:29
User entered 'Day 3'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-05T09:44:28', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f511775a-15b9-4628-9a01-d91249bd1d97' User entered 'None (0)'	System	05 Oct 2020 14:44:58
	System	05 Oct 2020 14:44:58

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-05T09:44:31', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f511775a-15b9-4628-9a01-d91249bd1d97' User entered 'None (0)'	System	05 Oct 2020 14:44:58
	System	05 Oct 2020 14:44:58

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-05T09:44:35', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f511775a-15b9-4628-9a01-d91249bd1d97' User entered 'None (0)'	System	05 Oct 2020 14:44:58
	System	05 Oct 2020 14:44:58

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-05T09:44:38', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f511775a-15b9-4628-9a01-d91249bd1d97' User entered 'None (0)'	System	05 Oct 2020 14:44:58
	System	05 Oct 2020 14:44:58

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-05T09:44:40', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f511775a-15b9-4628-9a01-d91249bd1d97' User entered 'None (0)'	System	05 Oct 2020 14:44:58
	System	05 Oct 2020 14:44:58

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-05T09:44:42', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f511775a-15b9-4628-9a01-d91249bd1d97' User entered 'None (0)'	System	05 Oct 2020 14:44:58
	System	05 Oct 2020 14:44:58

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-05T09:44:46', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f511775a-15b9-4628-9a01-d91249bd1d97'	System	05 Oct 2020 14:44:58
User entered 'No (N)'	System	05 Oct 2020 14:44:58

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-05T09:44:54', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f511775a-15b9-4628-9a01-d91249bd1d97' User entered '05 Oct 2020 09:44'	System	05 Oct 2020 14:44:58
	System	05 Oct 2020 14:44:58

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	02 Oct 2020 19:18:29
User entered 'Day 4'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T09:07:54', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd54fec33-937c-49da-9964-105d7ff2a8d7' User entered 'None (0)'	System	06 Oct 2020 14:08:15
	System	06 Oct 2020 14:08:15

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T09:07:56', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd54fec33-937c-49da-9964-105d7ff2a8d7' User entered 'None (0)'	System	06 Oct 2020 14:08:15
	System	06 Oct 2020 14:08:15

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T09:07:58', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd54fec33-937c-49da-9964-105d7ff2a8d7' User entered 'None (0)'	System	06 Oct 2020 14:08:15
	System	06 Oct 2020 14:08:15

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T09:08:01', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd54fec33-937c-49da-9964-105d7ff2a8d7' User entered 'None (0)'	System	06 Oct 2020 14:08:15
	System	06 Oct 2020 14:08:15

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T09:08:04', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd54fec33-937c-49da-9964-105d7ff2a8d7' User entered 'None (0)'	System	06 Oct 2020 14:08:15
	System	06 Oct 2020 14:08:15

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T09:08:06', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd54fec33-937c-49da-9964-105d7ff2a8d7' User entered 'None (0)'	System	06 Oct 2020 14:08:15
	System	06 Oct 2020 14:08:15

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T09:08:10', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd54fec33-937c-49da-9964-105d7ff2a8d7'	System	06 Oct 2020 14:08:15
User entered 'No (N)'	System	06 Oct 2020 14:08:15

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T09:08:13', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd54fec33-937c-49da-9964-105d7ff2a8d7' User entered '06 Oct 2020 09:08'	System	06 Oct 2020 14:08:15
	System	06 Oct 2020 14:08:15

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	02 Oct 2020 19:18:29
User entered 'Day 5'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T17:06:57', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f742412b-f92d-43da-bb1c-4c776ce6cbcf' User entered 'None (0)'	System	06 Oct 2020 22:08:07
	System	06 Oct 2020 22:08:07

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T17:07:41', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f742412b-f92d-43da-bb1c-4c776ce6cbcf' User entered 'None (0)'	System	06 Oct 2020 22:08:07
	System	06 Oct 2020 22:08:07

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T17:07:40', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f742412b-f92d-43da-bb1c-4c776ce6cbcf' User entered 'None (0)'	System	06 Oct 2020 22:08:07
	System	06 Oct 2020 22:08:07

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T17:07:38', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f742412b-f92d-43da-bb1c-4c776ce6cbcf' User entered 'None (0)'	System	06 Oct 2020 22:08:07
	System	06 Oct 2020 22:08:07

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T17:07:37', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f742412b-f92d-43da-bb1c-4c776ce6cbcf' User entered 'None (0)'	System	06 Oct 2020 22:08:07
	System	06 Oct 2020 22:08:07

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T17:07:47', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f742412b-f92d-43da-bb1c-4c776ce6cbcf' User entered 'None (0)'	System	06 Oct 2020 22:08:07
	System	06 Oct 2020 22:08:07

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T17:07:52', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f742412b-f92d-43da-bb1c-4c776ce6cbcf' User entered 'No (N)'	System	06 Oct 2020 22:08:07
	System	06 Oct 2020 22:08:07

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-06T17:08:04', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f742412b-f92d-43da-bb1c-4c776ce6cbcf' User entered '06 Oct 2020 17:08'	System	06 Oct 2020 22:08:07
	System	06 Oct 2020 22:08:07

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	02 Oct 2020 19:18:29
User entered 'Day 6'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-07T12:01:25', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '5898d984-a415-43b8-a016-7e617e114081' User entered 'None (0)'	System	07 Oct 2020 17:02:23
	System	07 Oct 2020 17:02:23

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-07T12:01:32', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '5898d984-a415-43b8-a016-7e617e114081' User entered 'None (0)'	System	07 Oct 2020 17:02:23
	System	07 Oct 2020 17:02:23

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-07T12:01:35', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '5898d984-a415-43b8-a016-7e617e114081' User entered 'None (0)'	System	07 Oct 2020 17:02:23
	System	07 Oct 2020 17:02:23

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-07T12:01:39', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '5898d984-a415-43b8-a016-7e617e114081' User entered 'None (0)'	System	07 Oct 2020 17:02:23
	System	07 Oct 2020 17:02:23

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-07T12:01:43', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '5898d984-a415-43b8-a016-7e617e114081' User entered 'None (0)'	System	07 Oct 2020 17:02:23
	System	07 Oct 2020 17:02:23

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-07T12:01:46', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '5898d984-a415-43b8-a016-7e617e114081' User entered 'None (0)'	System	07 Oct 2020 17:02:23
	System	07 Oct 2020 17:02:23

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-07T12:01:49', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '5898d984-a415-43b8-a016-7e617e114081' User entered 'No (N)'	System	07 Oct 2020 17:02:23
	System	07 Oct 2020 17:02:23

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-07T12:01:54', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '5898d984-a415-43b8-a016-7e617e114081' User entered '07 Oct 2020 12:01'	System	07 Oct 2020 17:02:23
	System	07 Oct 2020 17:02:23

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	02 Oct 2020 19:18:29
User entered 'Day 7'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-08T12:02:27', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '625065bb-ec88-46d4-91bc-f7923ff76bbf' User entered 'None (0)'	System	08 Oct 2020 17:03:24
	System	08 Oct 2020 17:03:24

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-08T12:02:30', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '625065bb-ec88-46d4-91bc-f7923ff76bbf' User entered 'None (0)'	System	08 Oct 2020 17:03:24
	System	08 Oct 2020 17:03:24

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-08T12:02:33', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '625065bb-ec88-46d4-91bc-f7923ff76bbf' User entered 'None (0)'	System	08 Oct 2020 17:03:24
	System	08 Oct 2020 17:03:24

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-08T12:02:36', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '625065bb-ec88-46d4-91bc-f7923ff76bbf' User entered 'None (0)'	System	08 Oct 2020 17:03:24
	System	08 Oct 2020 17:03:24

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-08T12:02:38', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '625065bb-ec88-46d4-91bc-f7923ff76bbf' User entered 'None (0)'	System	08 Oct 2020 17:03:24
	System	08 Oct 2020 17:03:24

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-08T12:02:42', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '625065bb-ec88-46d4-91bc-f7923ff76bbf' User entered 'None (0)'	System	08 Oct 2020 17:03:24
	System	08 Oct 2020 17:03:24

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-08T12:02:45', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '625065bb-ec88-46d4-91bc-f7923ff76bbf' User entered 'No (N)'	System	08 Oct 2020 17:03:24
	System	08 Oct 2020 17:03:24

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-08T12:02:50', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '625065bb-ec88-46d4-91bc-f7923ff76bbf' User entered '08 Oct 2020 12:02'	System	08 Oct 2020 17:03:24
	System	08 Oct 2020 17:03:24

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 19:18:29

US3212181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:48:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 19:18:29

US3212181

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:28:16

US3212181

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '09 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	14 Dec 2020 17:30:41
User entered '9 Oct 2020'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:28:16

US3212181

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:28:16

US3212181

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:28:16

US3212181

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:28:22

US3212181

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered 'I'	System	26 Oct 2020 17:28:22

US3212181

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:28:35

US3212181

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '16 Oct 2020'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:28:35

US3212181

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:28:35

US3212181

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:28:35

US3212181

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:28:41

US3212181

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered 'I'	System	26 Oct 2020 17:28:41

US3212181

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:28:52

US3212181

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '23 Oct 2020'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:28:52

US3212181

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:28:52

US3212181

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:28:52

US3212181

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:28:56

US3212181

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered 'I'	System	26 Oct 2020 17:28:56

US3212181

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 18:09:29

US3212181

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered '27 Oct 2020'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 18:09:29

US3212181

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

[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 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 18:09:29

US3212181

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'VISIT3'	System	27 Oct 2020 18:09:29

US3212181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 18:09:56

US3212181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered '27 Oct 2020'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 18:09:56

US3212181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered '12:23'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 18:09:56

US3212181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered '27 Oct 2020 12:23'	System	27 Oct 2020 18:09:56

US3212181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered '97.5' F	Laura Ngansop Djampou (b) (4)	27 Oct 2020 18:09:56

US3212181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 18:09:56

US3212181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered empty.	Laura Ngansop Djampou (b) (4)	27 Oct 2020 18:09:56

US3212181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered '78'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 18:09:56

US3212181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'bpm'	System	27 Oct 2020 18:09:56

US3212181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered '14'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 18:09:56

US3212181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'breaths/min'	System	27 Oct 2020 18:09:56

US3212181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered '134'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 18:09:56

US3212181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'mmHg'	System	27 Oct 2020 18:09:56

US3212181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered '75'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 18:09:56

US3212181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'mmHg'	System	27 Oct 2020 18:09:56

US3212181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02

US3212181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02

US3212181

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:48:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 18:10:07

US3212181

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:48:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '27 Oct 2020'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 18:10:07

US3212181

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 18:10:24

US3212181

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '27 Oct 2020'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 18:10:24

US3212181

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '12:52'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 18:10:24

US3212181

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered '27 Oct 2020 12:52'	System	27 Oct 2020 18:10:24

US3212181

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 18:10:28

US3212181

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'I'	System	27 Oct 2020 18:10:28

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 64'	System	14 Aug 2020 19:58:26

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-14T17:17:24', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '6e74aede-cf27-48fd-839f-d651c0490665'	System	14 Oct 2020 22:17:40
User entered 'No (N)'	System	14 Oct 2020 22:17:40

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-14T17:17:32', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '6e74aede-cf27-48fd-839f-d651c0490665'	System	14 Oct 2020 22:17:40
User entered 'No (N)'	System	14 Oct 2020 22:17:40

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-14T17:17:38', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '6e74aede-cf27-48fd-839f-d651c0490665' User entered '14 Oct 2020 17:17:38'	System	14 Oct 2020 22:17:40
	System	14 Oct 2020 22:17:40

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 19:58:26

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 71'	System	14 Aug 2020 19:58:26

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-21T09:05:50', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0020dc69-1e6e-4cb6-ba11-4bb3b5ef703e' User entered 'No (N)'	System	21 Oct 2020 14:06:07
	System	21 Oct 2020 14:06:07

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-21T09:05:53', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0020dc69-1e6e-4cb6-ba11-4bb3b5ef703e' User entered 'No (N)'	System	21 Oct 2020 14:06:07
	System	21 Oct 2020 14:06:07

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-21T09:06:03', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '0020dc69-1e6e-4cb6-ba11-4bb3b5ef703e' User entered '21 Oct 2020 09:06:03'	System	21 Oct 2020 14:06:07
	System	21 Oct 2020 14:06:07

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 19:58:26

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 78'	System	14 Aug 2020 19:58:26

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-28T14:41:52', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'fd3729e4-c8dc-4122-a95e-3e4c07ee67ed' User entered 'No (N)'	System	28 Oct 2020 19:42:17
	System	28 Oct 2020 19:42:17

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-28T14:41:56', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'fd3729e4-c8dc-4122-a95e-3e4c07ee67ed'	System	28 Oct 2020 19:42:17
User entered 'No (N)'	System	28 Oct 2020 19:42:17

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-10-28T14:42:16', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'fd3729e4-c8dc-4122-a95e-3e4c07ee67ed' User entered '28 Oct 2020 14:42:16'	System	28 Oct 2020 19:42:17
	System	28 Oct 2020 19:42:17

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 19:58:26

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 92'	System	14 Aug 2020 19:58:26

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-11-11T09:34:48', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '151d876d-5c91-4c38-bc89-11bc53ef15b6' User entered 'No (N)'	System	11 Nov 2020 15:35:31
	System	11 Nov 2020 15:35:31

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-11-11T09:34:59', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '151d876d-5c91-4c38-bc89-11bc53ef15b6' User entered 'No (N)'	System	11 Nov 2020 15:35:31
	System	11 Nov 2020 15:35:31

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-11-11T09:35:27', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '151d876d-5c91-4c38-bc89-11bc53ef15b6' User entered '11 Nov 2020 09:35:27'	System	11 Nov 2020 15:35:31
	System	11 Nov 2020 15:35:31

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 19:58:26

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered 'Day 99'	System	14 Aug 2020 19:58:26

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-11-18T14:37:05', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '005978d2-70a1-4f84-894a-9ca39b7a1ad7' User entered 'No (N)'	System	18 Nov 2020 20:37:20
	System	18 Nov 2020 20:37:20

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-11-18T14:37:11', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '005978d2-70a1-4f84-894a-9ca39b7a1ad7'	System	18 Nov 2020 20:37:20
User entered 'No (N)'	System	18 Nov 2020 20:37:20

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-11-18T14:37:17', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '005978d2-70a1-4f84-894a-9ca39b7a1ad7' User entered '18 Nov 2020 14:37:17'	System	18 Nov 2020 20:37:20
	System	18 Nov 2020 20:37:20

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 19:58:26

US3212181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:27:49
Data entry locked.	System	14 Aug 2020 19:58:26
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 19:58:26

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-11-22T00:02:04', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'ccd01734-07af-4b19-b3f8-68b4c7dbb84e' User entered 'No (N)'	System	22 Nov 2020 06:02:20
	System	22 Nov 2020 06:02:20

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Have you been exposed to someone with 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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-11-22T00:02:09', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'ccd01734-07af-4b19-b3f8-68b4c7dbb84e' User entered 'No (N)'	System	22 Nov 2020 06:02:20

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-11-22T00:02:14', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'ccd01734-07af-4b19-b3f8-68b4c7dbb84e' User entered '22 Nov 2020 00:02:14'	System	22 Nov 2020 06:02:20
	System	22 Nov 2020 06:02:20

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-11-30T08:35:45', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '6cbb3749-5de1-426a-89aa-02f8018999a6'	System	30 Nov 2020 14:36:02
User entered 'No (N)'	System	30 Nov 2020 14:36:02

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Have you been exposed to someone with 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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-11-30T08:35:51', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '6cbb3749-5de1-426a-89aa-02f8018999a6'	System	30 Nov 2020 14:36:02
User entered 'No (N)'	System	30 Nov 2020 14:36:02

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-11-30T08:35:58', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '6cbb3749-5de1-426a-89aa-02f8018999a6' User entered '30 Nov 2020 08:35:58'	System	30 Nov 2020 14:36:02
	System	30 Nov 2020 14:36:02

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-12-06T14:18:39', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '3095e03d-39a1-4c88-b6dd-d8ae806cbc9a' User entered 'No (N)'	System	06 Dec 2020 20:18:51
	System	06 Dec 2020 20:18:51

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Have you been exposed to someone with 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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-12-06T14:18:44', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '3095e03d-39a1-4c88-b6dd-d8ae806cbc9a' User entered 'No (N)'	System	06 Dec 2020 20:18:51
	System	06 Dec 2020 20:18:51

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-12-06T14:18:48', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '3095e03d-39a1-4c88-b6dd-d8ae806cbc9a' User entered '06 Dec 2020 14:18:48'	System	06 Dec 2020 20:18:51
	System	06 Dec 2020 20:18:51

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-12-14T16:11:39', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'ce7fdd8b-de5c-4f7a-9e95-01d174f07427'	System	14 Dec 2020 22:11:57
User entered 'No (N)'	System	14 Dec 2020 22:11:57

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Have you been exposed to someone with 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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-12-14T16:11:47', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'ce7fdd8b-de5c-4f7a-9e95-01d174f07427'	System	14 Dec 2020 22:11:57
User entered 'No (N)'	System	14 Dec 2020 22:11:57

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-12-14T16:11:54', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'ce7fdd8b-de5c-4f7a-9e95-01d174f07427' User entered '14 Dec 2020 16:11:54'	System	14 Dec 2020 22:11:57
	System	14 Dec 2020 22:11:57

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-12-21T08:11:45', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'cacb6ac-a552-491a-89c5-cabba4df7ead' User entered 'No (N)'	System	21 Dec 2020 15:12:13
	System	21 Dec 2020 15:12:13

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Have you been exposed to someone with 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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-12-21T08:11:57', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'cacb6ac-a552-491a-89c5-cabba4df7ead' User entered 'No (N)'	System	21 Dec 2020 15:12:13
	System	21 Dec 2020 15:12:13

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-12-21T08:12:06', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'cacb6ac-a552-491a-89c5-cabba4df7ead' User entered '21 Dec 2020 08:12:06'	System	21 Dec 2020 15:12:13
	System	21 Dec 2020 15:12:13

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-12-28T11:17:25', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '7cef0a41-08ba-42a0-b559-2925a0be69fa' User entered 'No (N)'	System	28 Dec 2020 17:17:45
	System	28 Dec 2020 17:17:45

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Have you been exposed to someone with 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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-12-28T11:17:29', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '7cef0a41-08ba-42a0-b559-2925a0be69fa'	System	28 Dec 2020 17:17:45
User entered 'No (N)'	System	28 Dec 2020 17:17:45

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2020-12-28T11:17:43', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '7cef0a41-08ba-42a0-b559-2925a0be69fa' User entered '28 Dec 2020 11:17:43'	System	28 Dec 2020 17:17:45
	System	28 Dec 2020 17:17:45

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-01-03T09:44:30', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '4be098e5-8577-4e3a-b76c-e2361236539a' User entered 'No (N)'	System	03 Jan 2021 15:44:55
	System	03 Jan 2021 15:44:55

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Have you been exposed to someone with 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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-01-03T09:44:42', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '4be098e5-8577-4e3a-b76c-e2361236539a' User entered 'No (N)'	System	03 Jan 2021 15:44:55
	System	03 Jan 2021 15:44:55

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-01-03T09:44:50', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '4be098e5-8577-4e3a-b76c-e2361236539a' User entered '03 Jan 2021 09:44:50'	System	03 Jan 2021 15:44:55
	System	03 Jan 2021 15:44:55

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-01-11T09:26:41', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '42976473-6a3f-4030-8c89-daca24acba57'	System	11 Jan 2021 15:27:00
User entered 'No (N)'	System	11 Jan 2021 15:27:00

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Have you been exposed to someone with 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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-01-11T09:26:48', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '42976473-6a3f-4030-8c89-daca24acba57'	System	11 Jan 2021 15:27:00
User entered 'No (N)'	System	11 Jan 2021 15:27:00

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-01-11T09:26:58', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '42976473-6a3f-4030-8c89-daca24acba57' User entered '11 Jan 2021 09:26:58'	System	11 Jan 2021 15:27:00
	System	11 Jan 2021 15:27:00

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-01-19T12:45:57', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '7137d0bd-88f3-44ff-b280-99f73a10321e' User entered 'No (N)'	System	19 Jan 2021 18:46:10

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Have you been exposed to someone with 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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-01-19T12:46:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '7137d0bd-88f3-44ff-b280-99f73a10321e'	System	19 Jan 2021 18:46:10
User entered 'No (N)'	System	19 Jan 2021 18:46:10

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-01-19T12:46:05', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '7137d0bd-88f3-44ff-b280-99f73a10321e' User entered '19 Jan 2021 12:46:05'	System	19 Jan 2021 18:46:10
	System	19 Jan 2021 18:46:10

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-01-25T10:12:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd5573183-9983-4d85-80ae-265a49d95944'	System	25 Jan 2021 16:12:15
User entered 'No (N)'	System	25 Jan 2021 16:12:15

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Have you been exposed to someone with 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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-01-25T10:12:05', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd5573183-9983-4d85-80ae-265a49d95944'	System	25 Jan 2021 16:12:15
User entered 'No (N)'	System	25 Jan 2021 16:12:15

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-01-25T10:12:11', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'd5573183-9983-4d85-80ae-265a49d95944' User entered '25 Jan 2021 10:12:11'	System	25 Jan 2021 16:12:15

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-01-31T09:57:22', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f00ac139-2cbb-4db7-b74d-238f0269d932'	System	31 Jan 2021 15:57:44
User entered 'No (N)'	System	31 Jan 2021 15:57:44

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Have you been exposed to someone with 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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-01-31T09:57:37', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f00ac139-2cbb-4db7-b74d-238f0269d932'	System	31 Jan 2021 15:57:44
User entered 'No (N)'	System	31 Jan 2021 15:57:44

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-01-31T09:57:42', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f00ac139-2cbb-4db7-b74d-238f0269d932' User entered '31 Jan 2021 09:57:42'	System	31 Jan 2021 15:57:44
	System	31 Jan 2021 15:57:44

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-02-08T12:53:45', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '99088b02-67f8-493d-a74a-3a417c4ac319' User entered 'No (N)'	System	08 Feb 2021 18:53:59
	System	08 Feb 2021 18:53:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Have you been exposed to someone with 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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-02-08T12:53:52', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '99088b02-67f8-493d-a74a-3a417c4ac319'	System	08 Feb 2021 18:53:59
User entered 'No (N)'	System	08 Feb 2021 18:53:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-02-08T12:53:56', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '99088b02-67f8-493d-a74a-3a417c4ac319' User entered '08 Feb 2021 12:53:56'	System	08 Feb 2021 18:53:59
	System	08 Feb 2021 18:53:59

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-02-14T10:26:26', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'fd4bd653-f3a9-48e9-91bc-2fa01c27d6ad'	System	14 Feb 2021 16:26:45
User entered 'No (N)'	System	14 Feb 2021 16:26:45

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Have you been exposed to someone with 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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-02-14T10:26:35', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'fd4bd653-f3a9-48e9-91bc-2fa01c27d6ad'	System	14 Feb 2021 16:26:45
User entered 'No (N)'	System	14 Feb 2021 16:26:45

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-02-14T10:26:43', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'fd4bd653-f3a9-48e9-91bc-2fa01c27d6ad' User entered '14 Feb 2021 10:26:43'	System	14 Feb 2021 16:26:45
	System	14 Feb 2021 16:26:45

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-02-21T00:01:49', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f599f0b0-5a09-4b2e-9eec-4af4c532e0ce' User entered 'No (N)'	System	21 Feb 2021 06:02:26
	System	21 Feb 2021 06:02:26

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Have you been exposed to someone with 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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-02-21T00:01:52', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f599f0b0-5a09-4b2e-9eec-4af4c532e0ce' User entered 'No (N)'	System	21 Feb 2021 06:02:26

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-02-21T00:01:56', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'f599f0b0-5a09-4b2e-9eec-4af4c532e0ce' User entered '21 Feb 2021 00:01:56'	System	21 Feb 2021 06:02:26
	System	21 Feb 2021 06:02:26

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-03-01T08:14:34-06:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'af837af7-85a9-46c2-ab8f-3a35f101a2b2'	System	01 Mar 2021 14:14:51
User entered 'No (N)'	System	01 Mar 2021 14:14:51

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Have you been exposed to someone with 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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-03-01T08:14:41-06:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'af837af7-85a9-46c2-ab8f-3a35f101a2b2'	System	01 Mar 2021 14:14:51
User entered 'No (N)'	System	01 Mar 2021 14:14:51

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-03-01T08:14:49-06:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'af837af7-85a9-46c2-ab8f-3a35f101a2b2'	System	01 Mar 2021 14:14:51
User entered '01 Mar 2021 08:14:49'	System	01 Mar 2021 14:14:51

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-03-07T00:22:22-06:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '4591ad07-7a3b-4320-8408-edc5e1e9e563'	System	07 Mar 2021 06:22:36
User entered 'No (N)'	System	07 Mar 2021 06:22:36

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Have you been exposed to someone with 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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-03-07T00:22:26-06:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '4591ad07-7a3b-4320-8408-edc5e1e9e563'	System	07 Mar 2021 06:22:36
User entered 'No (N)'	System	07 Mar 2021 06:22:36

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-03-07T00:22:32-06:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '4591ad07-7a3b-4320-8408-edc5e1e9e563' User entered '07 Mar 2021 00:22:32'	System	07 Mar 2021 06:22:36
	System	07 Mar 2021 06:22:36

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-03-18T13:51:48-05:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '867f4c5c-f2cf-44c3-9848-75937048a224'	System	18 Mar 2021 18:52:09
User entered 'No (N)'	System	18 Mar 2021 18:52:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Have you been exposed to someone with 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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-03-18T13:51:55-05:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '867f4c5c-f2cf-44c3-9848-75937048a224'	System	18 Mar 2021 18:52:09
User entered 'No (N)'	System	18 Mar 2021 18:52:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-03-18T13:52:03-05:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '867f4c5c-f2cf-44c3-9848-75937048a224' User entered '18 Mar 2021 13:52:03'	System	18 Mar 2021 18:52:09
	System	18 Mar 2021 18:52:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-03-22T10:23:28-05:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'a15ecb07-0a52-4d05-8565-21cb3b9e6449'	System	22 Mar 2021 15:23:40
User entered 'No (N)'	System	22 Mar 2021 15:23:40

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Have you been exposed to someone with 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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-03-22T10:23:30-05:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'a15ecb07-0a52-4d05-8565-21cb3b9e6449'	System	22 Mar 2021 15:23:40
User entered 'No (N)'	System	22 Mar 2021 15:23:40

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-03-22T10:23:36-05:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'a15ecb07-0a52-4d05-8565-21cb3b9e6449'	System	22 Mar 2021 15:23:40
User entered '22 Mar 2021 10:23:36'	System	22 Mar 2021 15:23:40

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-04-08T16:10:13-05:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '9f84f8a7-f742-45ca-8982-c1e11a312ff1' User entered 'Yes (Y)'	System	08 Apr 2021 21:10:52
	System	08 Apr 2021 21:10:52

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Have you been exposed to someone with 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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-04-08T16:10:18-05:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '9f84f8a7-f742-45ca-8982-c1e11a312ff1' User entered 'No (N)'	System	08 Apr 2021 21:10:52

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-04-08T16:10:22-05:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '9f84f8a7-f742-45ca-8982-c1e11a312ff1' User entered 'No (N)'	System	08 Apr 2021 21:10:52
	System	08 Apr 2021 21:10:52

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-04-08T16:10:30-05:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '9f84f8a7-f742-45ca-8982-c1e11a312ff1' User entered 'Yes (Y)'	System	08 Apr 2021 21:10:52
	System	08 Apr 2021 21:10:52

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-04-08T16:10:34-05:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '9f84f8a7-f742-45ca-8982-c1e11a312ff1'	System	08 Apr 2021 21:10:52
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Apr 2021 21:10:52

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-04-08T16:10:38-05:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '9f84f8a7-f742-45ca-8982-c1e11a312ff1' User entered '08 Apr 2021 16:10:38'	System	08 Apr 2021 21:10:52
	System	08 Apr 2021 21:10:52

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-04-11T17:33:29-05:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '5f482393-ae63-44bc-92a8-abb42dd6e8fd' User entered 'No (N)'	System	11 Apr 2021 22:33:42
	System	11 Apr 2021 22:33:42

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Have you been exposed to someone with 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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-04-11T17:33:34-05:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '5f482393-ae63-44bc-92a8-abb42dd6e8fd'	System	11 Apr 2021 22:33:42
User entered 'No (N)'	System	11 Apr 2021 22:33:42

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-04-11T17:33:38-05:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '5f482393-ae63-44bc-92a8-abb42dd6e8fd' User entered '11 Apr 2021 17:33:38'	System	11 Apr 2021 22:33:42
	System	11 Apr 2021 22:33:42

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-04-21T18:05:02-05:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '6b0fbb5b-34c8-4d62-a826-65131b551b09'	System	21 Apr 2021 23:06:17
User entered 'No (N)'	System	21 Apr 2021 23:06:17

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Have you been exposed to someone with 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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-04-21T18:05:03-05:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '6b0fbb5b-34c8-4d62-a826-65131b551b09'	System	21 Apr 2021 23:06:17
User entered 'No (N)'	System	21 Apr 2021 23:06:17

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-04-21T18:05:07-05:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '6b0fbb5b-34c8-4d62-a826-65131b551b09'	System	21 Apr 2021 23:06:17
User entered '21 Apr 2021 18:05:07'	System	21 Apr 2021 23:06:17

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-04-25T20:02:21-05:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'a56728b4-0937-47c3-bf90-e9682ca8cc40'	System	26 Apr 2021 01:06:36
User entered 'No (N)'	System	26 Apr 2021 01:06:36

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Have you been exposed to someone with 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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-04-25T20:02:23-05:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'a56728b4-0937-47c3-bf90-e9682ca8cc40'	System	26 Apr 2021 01:06:36
User entered 'No (N)'	System	26 Apr 2021 01:06:36

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-04-25T20:02:28-05:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'a56728b4-0937-47c3-bf90-e9682ca8cc40'	System	26 Apr 2021 01:06:36
User entered '25 Apr 2021 20:02:28'	System	26 Apr 2021 01:06:36

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-05-02T00:02:29-05:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'b86d044e-bae4-48c3-a4ec-f393eeba3cdc'	System	02 May 2021 05:02:58
User entered 'No (N)'	System	02 May 2021 05:02:58

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

Have you been exposed to someone with 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 (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-05-02T00:02:33-05:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'b86d044e-bae4-48c3-a4ec-f393eeba3cdc'	System	02 May 2021 05:02:58
User entered 'No (N)'	System	02 May 2021 05:02:58

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-05-02T00:02:36-05:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: 'b86d044e-bae4-48c3-a4ec-f393eeba3cdc' User entered '02 May 2021 00:02:36'	System	02 May 2021 05:02:58
	System	02 May 2021 05:02:58

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 07:42:09

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 07:42:09

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 07:42:09

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 07:42:09

US3212181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:48:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:42:09
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 07:42:09

US3212181

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:48:57

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)	24 Apr 2021 08:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-03-01T08:15:08-06:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '10a83b6c-5314-4f19-aac8-95d814015381' User entered 'No (N)'	System	01 Mar 2021 14:15:39
	System	01 Mar 2021 14:15:39

US3212181

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:48:57

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:14:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9B8E041-8D91-4C91-A02C-AFF72F47BC37)', Time: '2021-03-01T08:15:34-06:00', User OID: 'PatientReportedOutcome (US3212181)', ODM File OID: '10a83b6c-5314-4f19-aac8-95d814015381' User entered '01 Mar 2021 08:15:34'	System	01 Mar 2021 14:15:39
	System	01 Mar 2021 14:15:39

US3212181

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	25 Nov 2020 16:51:06

US3212181

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '24 Nov 2020'	Laura Ngansop Djampou (b) (4)	25 Nov 2020 16:51:06

US3212181

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	25 Nov 2020 16:51:06

US3212181

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou (b) (4)	25 Nov 2020 16:51:06

US3212181

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	25 Nov 2020 16:51:13

US3212181

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered 'I'	System	25 Nov 2020 16:51:13

US3212181

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	29 Dec 2020 19:26:21

US3212181

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '28 Dec 2020'	Laura Ngansop Djampou (b) (4)	29 Dec 2020 19:26:21

US3212181

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	29 Dec 2020 19:26:21

US3212181

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou (b) (4)	29 Dec 2020 19:26:21

US3212181

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	29 Dec 2020 19:26:24

US3212181

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered 'I'	System	29 Dec 2020 19:26:24

US3212181

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Feb 2021 16:36:26

US3212181

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '29 Jan 2021'	Laura Ngansop Djampou (b) (4)	01 Feb 2021 16:36:26

US3212181

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	01 Feb 2021 16:36:26

US3212181

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou (b) (4)	01 Feb 2021 16:36:26

US3212181

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Feb 2021 16:36:15

US3212181

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered 'I'	System	01 Feb 2021 16:36:15

US3212181

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	10 Mar 2021 16:47:26

US3212181

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '02 Mar 2021'	Afifah Ayub (b) (4)	10 Mar 2021 16:47:26

US3212181

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Contact Made (CONTACT MADE)'	Afifah Ayub (b) (4)	10 Mar 2021 16:47:26

US3212181

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	10 Mar 2021 16:47:26

US3212181

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	10 Mar 2021 16:47:37

US3212181

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:55:56
User entered 'I'	System	10 Mar 2021 16:47:37

US3212181

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:02:17

US3212181

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered '23 Mar 2021'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:02:17

US3212181

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

[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 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:02:17

US3212181

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'VISIT4'	System	24 Mar 2021 15:02:17

US3212181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	30 Mar 2021 16:04:07

US3212181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered '23 Mar 2021'	Afifah Ayub (b) (4)	30 Mar 2021 16:04:07

US3212181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered '13:19'	Afifah Ayub (b) (4)	30 Mar 2021 16:04:07

US3212181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered '23 Mar 2021 13:19'	System	30 Mar 2021 16:04:07

US3212181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered '97.2' F	Afifah Ayub (b) (4)	30 Mar 2021 16:04:07

US3212181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	30 Mar 2021 16:04:07

US3212181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered empty.	Afifah Ayub (b) (4)	30 Mar 2021 16:04:07

US3212181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered '62'	Afifah Ayub (b) (4)	30 Mar 2021 16:04:07

US3212181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'bpm'	System	30 Mar 2021 16:04:07

US3212181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered '16'	Afifah Ayub (b) (4)	30 Mar 2021 16:04:07

US3212181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'breaths/min'	System	30 Mar 2021 16:04:07

US3212181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered '119'	Afifah Ayub (b) (4)	30 Mar 2021 16:04:07

US3212181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'mmHg'	System	30 Mar 2021 16:04:07

US3212181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered '68'	Afifah Ayub (b) (4)	30 Mar 2021 16:04:07

US3212181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'mmHg'	System	30 Mar 2021 16:04:07

US3212181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02

US3212181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02

US3212181

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:48:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:02:26

US3212181

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:48:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered empty.	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:02:26

US3212181

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:02:55

US3212181

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered '23 Mar 2021'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:02:55

US3212181

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered '14:04'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:02:55

US3212181

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered '23 Mar 2021 14:04'	System	24 Mar 2021 15:02:55

US3212181

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:11:56
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:03:02

US3212181

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:56:02
User entered 'I'	System	24 Mar 2021 15:03:02

US3212181

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	01 May 2021 18:40:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 19:01:08

US3212181

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	01 May 2021 18:40:46
User entered '29 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 19:01:08

US3212181

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	01 May 2021 18:40:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 19:01:08

US3212181

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	01 May 2021 18:40:46
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	30 Apr 2021 19:01:08

US3212181

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	01 May 2021 18:40:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 19:01:22

US3212181

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 19:01:22

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:48:57

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:36
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '18 Sep 2020'	Afifah Ayub (b) (4)	01 Apr 2021 16:07:48

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:48:57

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:36
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '14:02'	Afifah Ayub (b) (4)	01 Apr 2021 16:07:48

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:48:57

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:36
User entered '18 Sep 2020 14:02'	System	01 Apr 2021 16:07:48

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:48:57

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:36
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Afifah Ayub (b) (4)	01 Apr 2021 16:07:48

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:48:57

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:36
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	01 Apr 2021 16:07:48

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:48:57

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 16:07:57

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:48:57

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '18 Sep 2020'	Afifah Ayub (b) (4)	01 Apr 2021 16:07:57

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:48:57

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'I'	Afifah Ayub (b) (4)	01 Apr 2021 16:07:57

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:48:57

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 16:07:57

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:48:57

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:41
User entered empty.	System	01 Apr 2021 16:07:57

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:48:57

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 16:07:57

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:48:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 16:07:57

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:48:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 16:07:57

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:48:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 16:07:57

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:48:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 16:07:57

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:48:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 16:07:57

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:48:57

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 16:07:57

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:48:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 16:07:57

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:48:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 16:07:57

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:48:57

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 16:07:57

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:48:57

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 16:07:57

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:48:57

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 16:07:57

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:48:57

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 16:07:57

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:48:57

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 16:07:57

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:48:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 16:07:57

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:48:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 16:07:57

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:48:57

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 16:07:57

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:48:57

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:45
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '18 Sep 2020'	Afifah Ayub (b) (4)	01 Apr 2021 16:08:07

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:48:57

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:45
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	01 Apr 2021 16:08:07

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:48:57

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:45
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Afifah Ayub (b) (4)	01 Apr 2021 16:08:07

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:48:57

Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:45
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab: Sample dated 18-Sep-2020 is recorded under Covid-19 Assessment visit in EDC, however the same is reported as an "Unscheduled" Visit sample (Accession No: 1F600117922) in PPD Central lab, Preclarus Report. Please review and confirm the correct Visit Name and make updates in EDC and PPD Portal as appropriate. Else clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 09:52:39
Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab: Sample dated 18-Sep-2020 is recorded under Covid-19 Assessment visit in EDC, however the same is reported as an "Unscheduled" Visit sample (Accession No: 1F600117922) in PPD Central lab, Preclarus Report. Please review and confirm the correct Visit Name and make updates in EDC and PPD Portal as appropriate. Else clarify, Thank you.' answered with 'visit was unscheduled for NP swab, as there is no eCRF to capture NP swab in unscheduled visit in EDC it is documented in the COVID test folder' (Site from DM).	Heather Leary (b) (4) (b) (4)	15 Apr 2021 14:18:50
User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab: Sample dated 18-Sep-2020 is recorded under Covid-19 Assessment visit in EDC, however the same is reported as an "Unscheduled" Visit sample (Accession No: 1F600117922) in PPD Central lab, Preclarus Report. Please review and confirm the correct Visit Name and make updates in EDC and PPD Portal as appropriate. Else clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 06:17:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '18 Sep 2020'	Afifah Ayub (b) (4) (b) (4)	01 Apr 2021 16:08:07

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:48:57

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:45
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Afifah Ayub (b) (4)	01 Apr 2021 16:08:07

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:48:57

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:45
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 16:08:07

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:48:57

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:45
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Afifah Ayub (b) (4)	01 Apr 2021 16:08:07

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:48:57

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:45
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 16:08:07

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:48:57

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:45
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 16:08:07

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:48:57

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:45
User entered '0'	System	01 Apr 2021 16:08:07

US3212181

Folder: Covid-19 Assessment 18 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:48:57

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:27:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Afifah Ayub (b) (4)	01 Apr 2021 16:08:11

US3212181

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

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Heather Leary (b) (4)	21 Jan 2021 19:08:42

US3212181

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

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '21 Jan 2021'	Heather Leary (b) (4)	21 Jan 2021 19:08:42

US3212181

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

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

[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 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Clinic (Clinic)'	Heather Leary (b) (4)	21 Jan 2021 19:08:42

US3212181

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

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'UNBLND_DECIDE'	System	21 Jan 2021 19:08:42

US3212181

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

Form: Unblinding

Generated On: 09 Jun 2021 15:48:57

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '21 Jan 2021'	Heather Leary (b) (4)	21 Jan 2021 19:09:14

US3212181

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

Form: Unblinding

Generated On: 09 Jun 2021 15:48:57

[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 05:29:51
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:29:31
User entered '0'	(b) (4) Heather Leary (b) (4)	22 Apr 2021 15:04:32
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 05:04:07

US3212181

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

Form: Unblinding

Generated On: 09 Jun 2021 15:48:57

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Heather Leary (b) (4)	21 Jan 2021 19:09:14

US3212181

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

Form: Unblinding

Generated On: 09 Jun 2021 15:48:57

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User closed query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 19:27:00
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:29:31
Query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'done' (Site from DM).	Heather Leary (b) (4)	22 Apr 2021 15:04:48
User entered 'Amendment 6 or later (Amendment 6 or later)'	Heather Leary (b) (4)	22 Apr 2021 15:04:32
User opened query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 07:46:47
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:04:07

US3212181

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

Form: Unblinding

Generated On: 09 Jun 2021 15:48:57

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '21 Jan 2021'	Heather Leary (b) (4)	21 Jan 2021 19:09:14

US3212181

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

Form: Unblinding

Generated On: 09 Jun 2021 15:48:57

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Placebo (Placebo)'	Heather Leary (b) (4)	21 Jan 2021 19:09:14

US3212181

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

Form: Unblinding

Generated On: 09 Jun 2021 15:48:57

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Placebo (Placebo)'	Heather Leary (b) (4)	21 Jan 2021 19:09:14

US3212181

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

Form: Unblinding

Generated On: 09 Jun 2021 15:48:57

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Placebo (Placebo)'	Heather Leary (b) (4)	21 Jan 2021 19:09:14

US3212181

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

Form: Unblinding

Generated On: 09 Jun 2021 15:48:57

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Heather Leary (b) (4)	21 Jan 2021 19:09:14

US3212181

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

Form: Unblinding

Generated On: 09 Jun 2021 15:48:57

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered '1'	System	21 Jan 2021 19:09:14

US3212181

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

Form: Unblinding

Generated On: 09 Jun 2021 15:48:57

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'I'	System	21 Jan 2021 19:09:14

US3212181

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:48:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered missing code ND - Not Done.	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:48:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered missing code ND - Not Done.	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:48:57

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered empty.	System	21 Jan 2021 19:10:22
DataPoint set to visible.	System	21 Jan 2021 19:09:14

US3212181

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:48:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered missing code ND - Not Done.	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:48:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered missing code ND - Not Done.	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:48:57

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered empty.	System	21 Jan 2021 19:10:22
DataPoint set to visible.	System	21 Jan 2021 19:09:14

US3212181

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User accepted default value 'Pre-Dose (PREDOSE)'	Heather Leary (b) (4) (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '21 Jan 2021'	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '10:51'	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered '21 Jan 2021 10:51'	System	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '97.0' F	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Oral (Oral)'	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '71'	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'bpm'	System	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '14'	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'breaths/min'	System	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '126'	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'mmHg'	System	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '80'	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'mmHg'	System	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:48:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered missing code ND - Not Done.	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:48:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered missing code ND - Not Done.	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:48:57

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered empty.	System	21 Jan 2021 19:10:22
DataPoint set to visible.	System	21 Jan 2021 19:09:14

US3212181

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User accepted default value 'Post-Dose (POSTDOSE)'	Heather Leary (b) (4) (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '21 Jan 2021'	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '12:53'	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered '21 Jan 2021 12:53'	System	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '98.0' F	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Oral (Oral)'	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '65'	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'bpm'	System	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '17'	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'breaths/min'	System	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '130'	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'mmHg'	System	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '82'	Heather Leary (b) (4)	21 Jan 2021 19:10:22

US3212181

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'mmHg'	System	21 Jan 2021 19:10:22

US3212181

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:48:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Heather Leary (b) (4)	21 Jan 2021 19:10:32

US3212181

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:48:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '21 Jan 2021'	Heather Leary (b) (4)	21 Jan 2021 19:10:32

US3212181

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

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:17:50
User entered 'Yes (Y)'	Heather Leary (b) (4)	21 Jan 2021 19:10:44

US3212181

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

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:17:50
User entered empty.	Heather Leary (b) (4)	21 Jan 2021 19:10:44

US3212181

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

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:17:50
User entered empty.	Heather Leary (b) (4)	21 Jan 2021 19:10:44

US3212181

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

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'mRNA-1273'	System	21 Jan 2021 19:10:44
DataPoint set to visible.	System	21 Jan 2021 19:09:14

US3212181

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

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:17:50
User entered '21 Jan 2021'	Heather Leary (b) (4)	21 Jan 2021 19:10:44

US3212181

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

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:17:50
User entered '12:23'	Heather Leary (b) (4)	21 Jan 2021 19:10:44

US3212181

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

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered '21 Jan 2021 12:23'	System	21 Jan 2021 19:10:44

US3212181

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

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:17:50
User entered 'Right Arm (RIGHT ARM)'	Heather Leary (b) (4)	21 Jan 2021 19:10:44

US3212181

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

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:17:50
User entered 'ONCE'	System	21 Jan 2021 19:10:44

US3212181

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

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'INTRAMUSCULAR'	System	21 Jan 2021 19:10:44

US3212181

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Heather Leary (b) (4)	21 Jan 2021 19:11:06

US3212181

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '21 Jan 2021'	Heather Leary (b) (4)	21 Jan 2021 19:11:06

US3212181

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '11:32'	Heather Leary (b) (4)	21 Jan 2021 19:11:06

US3212181

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered '21 Jan 2021 11:32'	System	21 Jan 2021 19:11:06

US3212181

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:48:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Heather Leary (b) (4)	21 Jan 2021 19:11:14

US3212181

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '21 Jan 2021'	Heather Leary (b) (4)	21 Jan 2021 19:11:14

US3212181

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:48:57

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '11:28'	Heather Leary (b) (4)	21 Jan 2021 19:11:14

US3212181

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered '21 Jan 2021 11:28'	System	21 Jan 2021 19:11:14

US3212181

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

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Heather Leary (b) (4)	21 Jan 2021 19:11:21

US3212181

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

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'I'	System	21 Jan 2021 19:11:21

US3212181

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	29 Jan 2021 15:15:30

US3212181

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '28 Jan 2021'	Laura Ngansop Djampou (b) (4)	29 Jan 2021 15:15:30

US3212181

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	29 Jan 2021 15:15:30

US3212181

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou (b) (4)	29 Jan 2021 15:15:30

US3212181

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	29 Jan 2021 15:15:37

US3212181

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'I'	System	29 Jan 2021 15:15:37

US3212181

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered '1'	System	29 Jan 2021 15:15:37
DataPoint set to visible.	System	29 Jan 2021 15:15:37

US3212181

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:37:52

US3212181

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '23 Feb 2021'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:37:52

US3212181

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

[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 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:37:52

US3212181

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'OLD29'	System	24 Feb 2021 15:37:52

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User accepted default value 'Pre-Dose (PREDOSE)'	Laura Ngansop Djampou	24 Feb 2021 15:39:14
	(b) (4)	

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '23 Feb 2021'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '12:05'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered '23 Feb 2021 12:05'	System	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '98.2' F	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '74'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'bpm'	System	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '15'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'breaths/min'	System	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '138'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'mmHg'	System	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '86'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:48:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'mmHg'	System	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User accepted default value 'Post-Dose (POSTDOSE)'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '23 Feb 2021'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '13:26'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered '23 Feb 2021 13:26'	System	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '97.9' F	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '70'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'bpm'	System	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '16'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'breaths/min'	System	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '139'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'mmHg'	System	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '88'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:48:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'mmHg'	System	24 Feb 2021 15:39:14

US3212181

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:48:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:26

US3212181

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:48:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '23 Feb 2021'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:26

US3212181

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:44

US3212181

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:44

US3212181

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:44

US3212181

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'mRNA-1273'	System	24 Feb 2021 15:39:44
DataPoint set to visible.	System	29 Jan 2021 15:15:37

US3212181

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '23 Feb 2021'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:44

US3212181

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '12:56'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:44

US3212181

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered '23 Feb 2021 12:56'	System	24 Feb 2021 15:39:44

US3212181

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Right Arm (RIGHT ARM)'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:44

US3212181

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'ONCE'	System	24 Feb 2021 15:39:44

US3212181

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'INTRAMUSCULAR'	System	24 Feb 2021 15:39:44

US3212181

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	24 Feb 2021 15:39:51

US3212181

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'I'	System	24 Feb 2021 15:39:51

US3212181

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	02 Mar 2021 18:45:28

US3212181

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '02 Mar 2021'	Laura Ngansop Djampou (b) (4)	02 Mar 2021 18:45:28

US3212181

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	02 Mar 2021 18:45:28

US3212181

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:48:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou (b) (4)	02 Mar 2021 18:45:28

US3212181

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	02 Mar 2021 18:45:36

US3212181

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:48:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'I'	System	02 Mar 2021 18:45:36

US3212181

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:00:53

US3212181

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '23 Mar 2021'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:00:53

US3212181

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

[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 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:00:53

US3212181

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:48:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'OLD57'	System	24 Mar 2021 15:00:53

US3212181

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:01:34

US3212181

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '23 Mar 2021'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:01:34

US3212181

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '13:19'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:01:34

US3212181

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered '23 Mar 2021 13:19'	System	24 Mar 2021 15:01:34

US3212181

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '97.2' F	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:01:34

US3212181

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:01:34

US3212181

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:01:34

US3212181

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '62'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:01:34

US3212181

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'bpm'	System	24 Mar 2021 15:01:34

US3212181

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '16'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:01:34

US3212181

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'breaths/min'	System	24 Mar 2021 15:01:34

US3212181

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '119'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:01:34

US3212181

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'mmHg'	System	24 Mar 2021 15:01:34

US3212181

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '68'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:01:34

US3212181

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered 'mmHg'	System	24 Mar 2021 15:01:34

US3212181

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51

US3212181

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:48:57

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51

US3212181

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:48:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:01:52

US3212181

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:48:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '23 Mar 2021'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:01:52

US3212181

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:02:07

US3212181

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '23 Mar 2021'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:02:07

US3212181

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '14:04'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:02:07

US3212181

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:29:51
User entered '23 Mar 2021 14:04'	System	24 Mar 2021 15:02:07

US3212181

Folder: Unscheduled 18 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:48:57

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:16:59
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '18 Sep 2020'	Afifah Ayub (b) (4)	20 Oct 2020 15:39:22

US3212181

Folder: Unscheduled 18 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:48:57

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:16:59
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '0'	Afifah Ayub (b) (4)	20 Oct 2020 15:39:22

US3212181

Folder: Unscheduled 18 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:48:57

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:16:59
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '0'	Afifah Ayub (b) (4)	20 Oct 2020 15:39:22

US3212181

Folder: Unscheduled 18 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:48:57

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:16:59
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'I'	Afifah Ayub (b) (4)	20 Oct 2020 15:39:22

US3212181

Folder: Unscheduled 18 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:48:57

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:16:59
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '0'	Afifah Ayub (b) (4)	20 Oct 2020 15:39:22

US3212181

Folder: Unscheduled 18 Sep 2020

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:05
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	20 Oct 2020 15:39:39

US3212181

Folder: Unscheduled 18 Sep 2020

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:05
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-query; Thank you for the Accession number, since the sample was shipped, please provide the Tracking number with the shipping date to track the sample in PPD as the sample is still missing in GCL for the collection date 18SEP2020 Unscheduled.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 06:57:01
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-query; Thank you for the Accession number, since the sample was shipped, please provide the Tracking number with the shipping date to track the sample in PPD as the sample is still missing in GCL for the collection date 18SEP2020 Unscheduled.' answered with 'Accession number: 1F68256 this sample is in PPD Lab portal and has even generated a result. The sample has been received. No tracking necessary as the result is clearly in portal.' (Site from DM).	Reagan Reed (b) (4)	22 Jan 2021 18:30:18
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-query; Thank you for the Accession number, since the sample was shipped, please provide the Tracking number with the shipping date to track the sample in PPD as the sample is still missing in GCL for the collection date 18SEP2020 Unscheduled.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 16:10:10
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 18SEP2020 is recorded under Unscheduled visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 07:20:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 18SEP2020 is recorded under Unscheduled visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.'	Reagan Reed (b) (4)	07 Dec 2020 14:24:07
Antibody-mediated Immunogenicity: Sample dated 18SEP2020 is recorded under Unscheduled visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.'	(b) (4)	
'Accession: 1F68256 ' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 18SEP2020 is recorded under Unscheduled visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.'	(b) (4), (b) (6)	07 Dec 2020 07:07:50
(Site from DM). User entered '18 Sep 2020'		
	Afifah Ayub (b) (4)	20 Oct 2020 15:39:39
	(b) (4)	

US3212181

Folder: Unscheduled 18 Sep 2020

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:05
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '14:03'	Afifah Ayub (b) (4)	20 Oct 2020 15:39:39

US3212181

Folder: Unscheduled 18 Sep 2020

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:17:05
User entered '18 Sep 2020 14:03'	System	20 Oct 2020 15:39:39

US3212181

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:48:57

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:59:21
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:11
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 20:50:37

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 14:59:29
User entered 'USA-US115-2021-mRNA-1273-P301000017'	System	26 Mar 2021 14:58:41
User entered 'New'	(b) (4), (b) (6)	26 Mar 2021 14:58:41

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'IQVIA medical query-Case clarification required: Please query for any previous hospitalizations for depression and triggers' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 13:18:01
Query 'IQVIA medical query-Case clarification required: Please query for any previous hospitalizations for depression and triggers' answered with 'History of depression since 2016 - 1 attempted suicide at the age of 18.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 23:53:39
User opened query 'IQVIA medical query-Case clarification required: Please query for any previous hospitalizations for depression and triggers' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 20:43:24
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression worsened - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 19:40:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 19:40:32
Data point term sent to Coder	System	25 Mar 2021 19:39:40
User entered 'WORSENING OF DEPRESSION' reason for change: Data Entry Error	Heather Leary (b) (4)	25 Mar 2021 19:38:44
Data point term sent to Coder	System	23 Mar 2021 19:01:56
User entered 'Recurrence of Depression'	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
User entered '05 Mar 2021'	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:29:23
User entered empty.	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:29:29
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 15:48:25
User entered empty.	System	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: New Information	Heather Leary (b) (4)	25 Mar 2021 19:38:44
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 15:05:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Mar 2021 15:05:24
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:05:24
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 19:01:51
User entered empty.	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: New Information	Heather Leary (b) (4)	25 Mar 2021 15:30:30
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 15:05:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Mar 2021 15:05:24
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:05:24
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 19:01:51
User entered empty.	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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)	09 Apr 2021 11:12:09
User closed query 'Per CDM: Response noted. Please update data once available. Thank you' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 11:11:47
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 'DATE ADDED' (Site from System).	(b) (4), (b) (6)	09 Apr 2021 00:01:50
Query 'Per CDM: Response noted. Please update data once available. Thank you' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 00:01:39
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	09 Apr 2021 00:01:30
User opened query 'Per CDM: Response noted. Please update data once available. Thank you' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 09:23:23
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)	29 Mar 2021 09:22:45
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 'unable to reach patient as he has been admitted to a psychiatric hospital. will update when information is available ' (Site from System).	Reagan Reed (b) (4) (b) (4)	26 Mar 2021 16:04:57

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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). User entered '1' reason for change: New Information	System	25 Mar 2021 15:30:30
User entered '0'	Heather Leary (b) (4) (b) (4) Laura Ngansop Djampou (b) (4)	25 Mar 2021 15:30:30 23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm initial hospital admission date.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 13:17:48
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)	09 Apr 2021 13:17:42
User entered '24 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 00:01:30
Query 'PV Query: Please confirm initial hospital admission date.' answered with '24MAR2021' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 00:00:49
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 'Not done.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 00:00:38
User opened query 'PV Query: Please confirm initial hospital admission date.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 15:47:35
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)	02 Apr 2021 15:47:16
User entered empty.	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 13:17:51
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'UPDATED' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 00:01:59
User entered '08 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 00:01:30
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 15:47:56
User entered empty.	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 15:05:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Mar 2021 15:05:24
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:05:24
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 19:01:51
User entered empty.	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:05:42
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 15:05:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Mar 2021 15:05:24
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:05:24
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 19:01:51
User entered empty.	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User closed query 'PV Query: As the last dose of mRNA-1273, was given on 23 Feb 2021 please update the action taken with mRNA-1273 from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 16:26:12
Query 'PV Query: As the last dose of mRNA-1273, was given on 23 Feb 2021 please update the action taken with mRNA-1273 from none to not applicable.' answered with 'updated' (Site from Safety).	Jagruti Patel (b) (4)	05 Apr 2021 17:55:06
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4)	05 Apr 2021 17:54:55
User opened query 'PV Query: As the last dose of mRNA-1273, was given on 23 Feb 2021 please update the action taken with mRNA-1273 from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 15:49:19
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 15:05:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Mar 2021 15:05:24
User entered 'None (NONE)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:05:24
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 19:01:51
User entered empty.	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[None](#)

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	24 Mar 2021 15:05:24
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	23 Mar 2021 19:01:51
User entered '0'	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Laura Ngansop Djampou	24 Mar 2021 15:05:24
	(b) (4)	
User entered '0'	Laura Ngansop Djampou	23 Mar 2021 19:01:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Heather Leary (b) (4)	09 Apr 2021 19:50:18
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 15:48:42
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 15:05:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Mar 2021 15:05:24
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:05:24
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 19:01:51
User entered empty.	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
User entered empty.	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 15:49:01
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Mar 2021 16:02:53
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	25 Mar 2021 16:02:53
User entered 'Subject notified the site that he is admitted to the hospital for treatment.' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	25 Mar 2021 16:02:53
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Mar 2021 15:30:30
User entered empty.	Laura Ngansop Djampou (b) (4)	23 Mar 2021 19:01:51

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 15:30:30
User entered '0'	System	24 Mar 2021 15:05:24

US3212181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:48:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 19:01:51

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 15:05:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 15:05:44
Data point term sent to Coder	System	24 Mar 2021 15:05:12
User entered 'Insomnia'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
User entered '05 Mar 2021'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[None](#)

Audit	User	Time (GMT)
User entered '0'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
User entered empty.	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Laura Ngansop Djampou (b) (4)	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:48:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 15:04:18

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Adverse event](#)

Audit	User		Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	(b) (4)	09 Apr 2021 20:50:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	(b) (4)	09 Apr 2021 20:50:48
Data point term sent to Coder	System		09 Apr 2021 20:49:52
User entered 'anxiety'	Heather Leary (b) (4)	(b) (4)	09 Apr 2021 20:49:09
	(b) (4)		

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
User entered '24 Mar 2021'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 20:49:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 20:49:31
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Heather Leary (b) (4)	09 Apr 2021 20:49:31
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 20:49:09
User entered empty.	Heather Leary (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 20:49:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 20:49:31
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Heather Leary (b) (4)	09 Apr 2021 20:49:31
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 20:49:09
User entered empty.	Heather Leary (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 20:50:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 20:50:47
User entered 'None (NONE)' reason for change: Data Entry Error	Heather Leary (b) (4)	09 Apr 2021 20:50:47
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 20:49:09
User entered empty.	Heather Leary (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[None](#)

Audit	User	Time (GMT)
User entered '0'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 20:49:09

US3212181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:48:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 20:49:09

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:59:21
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:29:24
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 20:51:06

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:48:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:32:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:27:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:27:24
Data point term sent to Coder	System	26 Oct 2020 17:30:46
User entered 'influenza vaccination'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:30:16

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:48:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:32:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 19:15:07
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	23 Dec 2020 15:54:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Reagan Reed (b) (4)	23 Dec 2020 15:54:17
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 23:19:23
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:30:16

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:48:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:32:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'immunization'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:30:16

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:48:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:32:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '0.5'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:30:16

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:48:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:32:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'mL (mL)'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:30:16

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:48:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:32:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:30:16

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:48:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:32:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'once (ONCE)'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:30:16

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:48:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:32:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:30:16

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:48:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:32:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Intramuscular (INTRAMUSCULAR)'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:30:16

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:48:57

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:32:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:30:16

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:32:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '22 Oct 2020'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:30:16

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:48:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:32:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '0'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:30:16

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:48:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:32:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:30:16

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:48:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:32:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '22 Oct 2020'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:30:16

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:48:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:32:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:30:16

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:48:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:32:40
User entered empty.	System	26 Oct 2020 17:30:16

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:48:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:32:40
User entered empty.	System	26 Oct 2020 17:30:16

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:48:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:32:40
User entered empty.	System	26 Oct 2020 17:30:16

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:48:57

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 18:19:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 18:19:46
Data point term sent to Coder Coding entries removed.	System Heather Leary (b) (4) (b) (4)	07 Apr 2021 18:18:42 07 Apr 2021 18:17:34
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	02 Apr 2021 20:08:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 18:55:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 18:55:48
Data point term sent to Coder User entered 'Escitalopram'	System Laura Ngansop Djampou (b) (4)	23 Mar 2021 18:54:43 23 Mar 2021 18:53:54

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:48:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Laura Ngansop Djampou	23 Mar 2021 18:53:54
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:48:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:47:31
	(b) (4), (b) (6)	08 Apr 2021 15:29:42
User closed query 'Per DM CLR: Please review if this refers to AE#1, Worsening of Depression. If so, please reconcile event terms so there is an appropriate match. Review and amend as appropriate. Else, provide clarification. ' (Site from DM).		
Query 'Per DM CLR: Please review if this refers to AE#1, Worsening of Depression. If so, please reconcile event terms so there is an appropriate match. Review and amend as appropriate. Else, provide clarification. ' answered with 'updated' (Site from DM).	Heather Leary (b) (4)	07 Apr 2021 18:17:51
Signature has been broken.	Heather Leary (b) (4)	07 Apr 2021 18:17:34
User entered 'worsening of DEPRESSION' reason for change: Data Entry Error	Heather Leary (b) (4)	07 Apr 2021 18:17:34
User opened query 'Per DM CLR: Please review if this refers to AE#1, Worsening of Depression. If so, please reconcile event terms so there is an appropriate match. Review and amend as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 08:06:00
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Depression'	Laura Ngansop Djampou (b) (4)	23 Mar 2021 18:53:54

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:48:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '10'	Laura Ngansop Djampou	23 Mar 2021 18:53:54
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:48:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'mg (mg)'	Laura Ngansop Djampou	23 Mar 2021 18:53:54
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:48:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou	23 Mar 2021 18:53:54
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:48:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'once daily (QD)'	Laura Ngansop Djampou	23 Mar 2021 18:53:54
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:48:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou	23 Mar 2021 18:53:54
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:48:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Oral (ORAL)'	Laura Ngansop Djampou	23 Mar 2021 18:53:54
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:48:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou	23 Mar 2021 18:53:54
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '06 Mar 2021'	Laura Ngansop Djampou (b) (4)	23 Mar 2021 18:53:54

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:48:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '0'	Laura Ngansop Djampou	23 Mar 2021 18:53:54
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:48:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou	23 Mar 2021 18:53:54
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:48:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou	23 Mar 2021 18:53:54
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:48:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	23 Mar 2021 18:53:54

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:48:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 18:53:54

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:48:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 18:53:54

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:48:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Mar 2021 18:53:54

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:48:57

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 18:19:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 18:19:46
Data point term sent to Coder	System	07 Apr 2021 18:18:43
Coding entries removed.	Heather Leary (b) (4)	07 Apr 2021 18:18:28
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 18:57:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 18:57:40
Data point term sent to Coder	System	23 Mar 2021 18:56:51
User entered 'Trazodone'	Laura Ngansop Djampou (b) (4)	23 Mar 2021 18:55:56

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:48:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 18:56:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 18:56:11
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	23 Mar 2021 18:56:11
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 18:55:56
User entered empty.	Laura Ngansop Djampou (b) (4)	23 Mar 2021 18:55:56

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:48:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:47:31
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	Priyanka Jakapure (3631 -08 Apr 2021 15:30:44 Jakapure@011)	
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Heather Leary (b) (4)	07 Apr 2021 18:18:53
Signature has been broken.	Heather Leary (b) (4)	07 Apr 2021 18:18:28
User entered 'insomnia' reason for change: Data Entry Error	Heather Leary (b) (4)	07 Apr 2021 18:18:28
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 08:06:24
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Sleep aid'	Laura Ngansop Djampou (b) (4)	23 Mar 2021 18:55:56

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:48:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '50'	Laura Ngansop Djampou	23 Mar 2021 18:55:56
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:48:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'mg (mg)'	Laura Ngansop Djampou	23 Mar 2021 18:55:56
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:48:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou	23 Mar 2021 18:55:56
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:48:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'once daily (QD)'	Laura Ngansop Djampou	23 Mar 2021 18:55:56
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:48:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou	23 Mar 2021 18:55:56
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:48:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Oral (ORAL)'	Laura Ngansop Djampou	23 Mar 2021 18:55:56
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:48:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou	23 Mar 2021 18:55:56
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '12 Mar 2021'	Laura Ngansop Djampou	23 Mar 2021 18:55:56
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:48:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '0'	Laura Ngansop Djampou	23 Mar 2021 18:55:56
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:48:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'Yes (Y)'	Laura Ngansop Djampou	23 Mar 2021 18:55:56
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:48:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered empty.	Laura Ngansop Djampou	23 Mar 2021 18:55:56
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:48:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Laura Ngansop Djampou	23 Mar 2021 18:55:56
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:48:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 18:55:56

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:48:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 18:55:56

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:48:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Mar 2021 18:55:56

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:48:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: DULOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: CYMBALTA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Apr 2021 18:58:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 18:58:47
Data point term sent to Coder	System	09 Apr 2021 18:57:32
User entered 'cymbalta'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 18:56:35

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:48:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
	(b) (4)	
User entered 'No (N)'	Heather Leary (b) (4)	09 Apr 2021 18:56:35
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:48:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered 'depression/anxiety'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:56:35

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:48:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered '90'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:56:35

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:48:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered 'mg (mg)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:56:35

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:48:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:10:42
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 18:56:35

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:48:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered 'once daily (QD)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:56:35

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:48:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:10:42
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 18:56:35

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:48:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
	(b) (4)	
User entered 'Oral (ORAL)'	Heather Leary (b) (4)	09 Apr 2021 18:56:35
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:48:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
	(b) (4)	
User entered empty.	Heather Leary (b) (4)	09 Apr 2021 18:56:35
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
	(b) (4)	
User entered '25 Mar 2021'	Heather Leary (b) (4)	09 Apr 2021 18:56:35
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:48:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered '0'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:56:35
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:48:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered 'Yes (Y)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:56:35

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:48:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
	(b) (4)	
User entered empty.	Heather Leary (b) (4)	09 Apr 2021 18:56:35
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:48:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
	(b) (4)	
User entered 'No (N)'	Heather Leary (b) (4)	09 Apr 2021 18:56:35
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:48:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 18:56:35

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:48:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 18:56:35

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:48:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Apr 2021 18:56:35

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:48:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: LITHIUM, PRODUCT: LITHIUM CARBONATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Apr 2021 12:41:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 12:41:16
Data point term sent to Coder	System	09 Apr 2021 18:57:32
User entered 'lithium carbonate'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 18:57:15

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:48:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
	(b) (4)	
User entered 'No (N)'	Heather Leary (b) (4)	09 Apr 2021 18:57:15
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:48:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered 'depression/anxiety'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:57:15

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:48:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered '300'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:57:15
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:48:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
	(b) (4)	
User entered 'mg (mg)'	Heather Leary (b) (4)	09 Apr 2021 18:57:15
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:48:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:10:42
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 18:57:15

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:48:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered 'once daily (QD)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:57:15

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:48:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:10:42
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 18:57:15

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:48:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered 'Oral (ORAL)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:57:15
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:48:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:10:42
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 18:57:15

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
	(b) (4)	
User entered '8 Apr 2021'	Heather Leary (b) (4)	09 Apr 2021 18:57:15
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:48:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered '0'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:57:15
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:48:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
	(b) (4)	
User entered 'Yes (Y)'	Heather Leary (b) (4)	09 Apr 2021 18:57:15
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:48:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
	(b) (4)	
User entered empty.	Heather Leary (b) (4)	09 Apr 2021 18:57:15
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:48:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered 'No (N)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:57:15

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:48:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 18:57:15

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:48:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 18:57:15

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:48:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Apr 2021 18:57:15

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:48:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIPRAZOLE, PRODUCTSYNONYM: ABILIFY - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Apr 2021 18:59:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 18:59:49
Data point term sent to Coder	System	09 Apr 2021 18:58:34
User entered 'abilify'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 18:57:47

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:48:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
	(b) (4)	
User entered 'No (N)'	Heather Leary (b) (4)	09 Apr 2021 18:57:47
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:48:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered 'depression/anxiety'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:57:47

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:48:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:10:42
User entered '5'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 18:57:47

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:48:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
	(b) (4)	
User entered 'mg (mg)'	Heather Leary (b) (4)	09 Apr 2021 18:57:47
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:48:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:10:42
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 18:57:47

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:48:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered 'once daily (QD)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:57:47

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:48:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
	(b) (4)	
User entered empty.	Heather Leary (b) (4)	09 Apr 2021 18:57:47
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:48:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered 'Oral (ORAL)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:57:47
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:48:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
	(b) (4)	
User entered empty.	Heather Leary (b) (4)	09 Apr 2021 18:57:47
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered '25 Mar 2021'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:57:47
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:48:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered '0'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:57:47
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:48:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered 'Yes (Y)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:57:47

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:48:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
	(b) (4)	
User entered empty.	Heather Leary (b) (4)	09 Apr 2021 18:57:47
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:48:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered 'No (N)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:57:47

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:48:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 18:57:47

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:48:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 18:57:47

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:48:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Apr 2021 18:57:47

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:48:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE, PRODUCTSYNONYM: REMERON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Apr 2021 18:59:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 18:59:49
Data point term sent to Coder	System	09 Apr 2021 18:58:35
User entered 'remeron'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 18:58:22

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:48:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:10:42
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 18:58:22

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:48:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered 'depression/anxiety'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:58:22

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:48:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
	(b) (4)	
User entered '30'	Heather Leary (b) (4)	09 Apr 2021 18:58:22
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:48:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
	(b) (4)	
User entered 'mg (mg)'	Heather Leary (b) (4)	09 Apr 2021 18:58:22
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:48:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
	(b) (4)	
User entered empty.	Heather Leary (b) (4)	09 Apr 2021 18:58:22
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:48:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered 'once daily (QD)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:58:22

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:48:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
	(b) (4)	
User entered empty.	Heather Leary (b) (4)	09 Apr 2021 18:58:22
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:48:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered 'Oral (ORAL)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:58:22
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:48:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
	(b) (4)	
User entered empty.	Heather Leary (b) (4)	09 Apr 2021 18:58:22
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:48:57

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered '25 Mar 2021'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:58:22
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:48:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered '0'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:58:22
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:48:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered 'Yes (Y)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:58:22

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:48:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
	(b) (4)	
User entered empty.	Heather Leary (b) (4)	09 Apr 2021 18:58:22
	(b) (4)	

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:48:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered 'No (N)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 18:58:22

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:48:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 18:58:22

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:48:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 18:58:22

US3212181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:48:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Apr 2021 18:58:22

US3212181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:48:57

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'No (N)'	Afifah Ayub (b) (4)	14 Aug 2020 20:51:15
	(b) (4)	

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'USA-US115-2021-MRNA-1273-P301000017'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'Yes (Y)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'No (N)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'No (N)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'Yes (Y)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'No (N)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'No (N)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'No (N)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:51:46
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:21
User entered 'Vicki'	(b) (4) System	06 Apr 2021 16:26:51

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:51:46
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:21
User entered 'Miller'	(b) (4) System	06 Apr 2021 16:26:51

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:51:46
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'US'	System	26 Mar 2021 15:00:30

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Apr 2021 15:51:58
User entered '3'	System	09 Apr 2021 13:19:36
User entered '2'	System	06 Apr 2021 16:26:51
User entered '1'	System	26 Mar 2021 15:00:30

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'USA-US115-2021-MRNA-1273-P301000017'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'Yes (Y)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'No (N)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'No (N)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'Yes (Y)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'No (N)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'No (N)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'No (N)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:51:46
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:21
User entered 'Vicki'	(b) (4) System	06 Apr 2021 16:26:51

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:51:46
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:21
User entered 'Miller'	(b) (4) System	06 Apr 2021 16:26:51

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:51:46
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'US'	System	26 Mar 2021 15:00:30

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Apr 2021 15:51:58
User entered '3'	System	09 Apr 2021 13:19:36
User entered '2'	System	06 Apr 2021 16:26:51
User entered '1'	System	26 Mar 2021 15:00:30

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:48:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered '26/Mar/2021 10:00'	System	26 Mar 2021 15:00:30

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:48:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:51:46
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'I'	(b) (4), (b) (6)	26 Mar 2021 15:00:30

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'USA-US115-2021-MRNA-1273-P301000017'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'Yes (Y)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'No (N)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'No (N)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'Yes (Y)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'No (N)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'No (N)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'No (N)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:51:46
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:21
User entered 'Vicki'	(b) (4) System	06 Apr 2021 16:26:51

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:51:46
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:21
User entered 'Miller'	(b) (4) System	06 Apr 2021 16:26:51

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:51:46
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'US'	System	26 Mar 2021 15:00:30

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Apr 2021 15:51:58
User entered '3'	System	09 Apr 2021 13:19:36
User entered '2'	System	06 Apr 2021 16:26:51
User entered '1'	System	26 Mar 2021 15:00:30

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:48:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:21
User entered '06/Apr/2021 12:26'	(b) (4) System	06 Apr 2021 16:26:51

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:48:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:51:46
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:21
User entered 'I'	(b) (4), (b) (6)	06 Apr 2021 16:26:51

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'USA-US115-2021-MRNA-1273-P301000017'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'Yes (Y)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'No (N)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'No (N)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'Yes (Y)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'No (N)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'No (N)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'No (N)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:51:46
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:21
User entered 'Vicki'	(b) (4) System	06 Apr 2021 16:26:51

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:51:46
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:21
User entered 'Miller'	(b) (4) System	06 Apr 2021 16:26:51

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:51:46
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'US'	System	26 Mar 2021 15:00:30

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Apr 2021 15:51:58
User entered '3'	System	09 Apr 2021 13:19:36
User entered '2'	System	06 Apr 2021 16:26:51
User entered '1'	System	26 Mar 2021 15:00:30

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:48:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	09 Apr 2021 14:16:08
User entered '09/Apr/2021 06:19'	(b) (4) System	09 Apr 2021 13:19:36

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:48:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:51:46
User signature succeeded.	Insiya Valika (b) (4)	09 Apr 2021 14:16:08
User entered 'I'	(b) (4), (b) (6)	09 Apr 2021 13:19:36

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'USA-US115-2021-MRNA-1273-P301000017'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'Yes (Y)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'No (N)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'No (N)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'Yes (Y)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'No (N)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'No (N)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 15:00:23
User entered 'No (N)'	System	26 Mar 2021 14:58:41

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:51:46
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:21
User entered 'Vicki'	(b) (4) System	06 Apr 2021 16:26:51

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:51:46
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:21
User entered 'Miller'	(b) (4) System	06 Apr 2021 16:26:51

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:51:46
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 20:08:01
User entered 'US'	System	26 Mar 2021 15:00:30

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:48:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Apr 2021 15:51:58
User entered '3'	System	09 Apr 2021 13:19:36
User entered '2'	System	06 Apr 2021 16:26:51
User entered '1'	System	26 Mar 2021 15:00:30

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:48:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered '12/Apr/2021 15:51'	(b) (4) System	12 Apr 2021 15:51:58

US3212181

Folder: SAE USA-US115-2021-MRNA-1273-P301000017

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:48:57

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.	Insiya Valika (b) (4)	16 Apr 2021 19:10:42
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:51:58