

US3212049 (Prod: DM Clinical Research - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:46:30

All time stamps listed in this document are displayed in GMT

US3212049

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 18:00:08

Generated On: 09 Jun 2021 15:46:30

[Participant ID](#)

US3212049

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

US3212049

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 17:55:57

Generated On: 09 Jun 2021 15:46:30

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

Visit date (dd MMM yyyy)	05 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3212049

Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Mar 2021 17:55:28

Generated On: 09 Jun 2021 15:46:30

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	72
Age Units	YEARS
Age (Derived)	72
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

US3212049

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Mar 2021 17:55:28

Generated On: 09 Jun 2021 15:46:30

Date of Informed Consent (*dd MMM yyyy*) 05 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input 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

US3212049

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Mar 2021 17:55:28

Generated On: 09 Jun 2021 15:46:30

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3212049

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Mar 2021 17:55:28

Generated On: 09 Jun 2021 15:46:30

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 06 Apr 2021 14:51:38

Generated On: 09 Jun 2021 15:46:30

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3212049

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 06 Apr 2021 14:51:38

Generated On: 09 Jun 2021 15:46:30

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3212049

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 06 Apr 2021 14:51:38

Generated On: 09 Jun 2021 15:46:30

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3212049

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 06 Apr 2021 14:51:38

Generated On: 09 Jun 2021 15:46:30

Condition	CANCEROUS STOMACH TUMOR
Start date (dd MMM yyyy)	UN UNK 2010
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 UNK 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

US3212049

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 06 Apr 2021 14:51:38

Generated On: 09 Jun 2021 15:46:30

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3212049

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 17:55:57

Generated On: 09 Jun 2021 15:46:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	05 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:00 (24 HR)
Vital Signs Date and Time (derived)	05 AUG 2020 12:00
Height (<i>xxx.x</i>)	75 in
Weight (<i>xxx.x</i>)	293 lb
BMI (<i>xxx.x</i>)	36.69906 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 17:55:28

Generated On: 09 Jun 2021 15:46:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 AUG 2020

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

US3212049

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Mar 2021 17:55:28

Generated On: 09 Jun 2021 15:46:30

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Mar 2021 17:55:28

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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	GOES TO PLACE OF WORSHIP ONCE A WEEK, GOES TO THE STORE 2+/WEEK, ATTENDS GATHERINGS OF 10 PEOPLE MORE THAN 2 TIMES A MONTH, EATS OUT AT RESTAURANTS 1+/WEEK

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 17:55:58

Generated On: 09 Jun 2021 15:46:30

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

Visit date (dd MMM yyyy)	05 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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US3212049

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Mar 2021 17:55:58

Generated On: 09 Jun 2021 15:46:30

What was the date of randomization? (dd MMM yyyy) 05 AUG 2020

What was the participant's randomization number? 184752

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 ☒

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Mar 2021 17:55:58

Generated On: 09 Jun 2021 15:46:30

Height	ND - Not Done
Weight	ND - Not Done

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 17:55:58

Generated On: 09 Jun 2021 15:46:30

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)	05 AUG 2020
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	05 AUG 2020 12:00
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)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 17:55:58

Generated On: 09 Jun 2021 15:46:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	05 AUG 2020
Time of assessment (00:00-23:59)	14:13 (24 HR)
Vital Signs Date and Time (derived)	05 AUG 2020 14:13
Temperature (xxx.x)	96.6 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 17:55:58

Generated On: 09 Jun 2021 15:46:30

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.

US3212049

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 17:55:58

Generated On: 09 Jun 2021 15:46:30

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) 05 AUG 2020

What was the treatment time? (00:00-23:59) 13:16 (24 HR)

Treatment Date and Time (derived) 05 AUG 2020 13:16

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

US3212049

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 17:55:58

Generated On: 09 Jun 2021 15:46:30

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

Collection date (dd MMM yyyy)	05 AUG 2020
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Collection time (00:00-23:59)	13:05 (24 HR)
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Collection date and time (derived)	05 AUG 2020 13:05
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US3212049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Mar 2021 17:55:57

Generated On: 09 Jun 2021 15:46:30

Collection date (dd MMM yyyy)			05 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:58	05 AUG 2020 12:58
Nasopharyngeal Swab 2	No		

US3212049

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:55:58

Generated On: 09 Jun 2021 15:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

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

96.6 °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

05 AUG 2020 13:49

PC Open Date & Time

05 AUG 2020 13:36

PC Close Date & Time

05 AUG 2020 16:06

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.9 °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	05 AUG 2020 18:21
PC Open Date & Time	05 AUG 2020 17:01
PC Close Date & Time	06 AUG 2020 11:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:30

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

06 AUG 2020 13:25

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:30

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 14:20

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 14:01

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:30

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

09 AUG 2020 14:15

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:30

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 13:47

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:30

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 15:34

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

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 ☒

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

1

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

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 AUG 2020 13:50

PC Open Date & Time

05 AUG 2020 13:36

PC Close Date & Time

05 AUG 2020 16:06

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

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

05 AUG 2020 18:22

PC Open Date & Time

05 AUG 2020 17:01

PC Close Date & Time

06 AUG 2020 11:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:30

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

06 AUG 2020 13:22

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:30

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

07 AUG 2020 14:20

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:30

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

08 AUG 2020 14:01

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:30

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

09 AUG 2020 14:15

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:30

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

10 AUG 2020 13:47

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:30

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

11 AUG 2020 15:33

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 13:51
PC Open Date & Time	05 AUG 2020 13:36
PC Close Date & Time	05 AUG 2020 16:06

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 18:23
PC Open Date & Time	05 AUG 2020 17:01
PC Close Date & Time	06 AUG 2020 11:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 13:22
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 14:19
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

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 ☒

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EAB) (1725)

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 14:02
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

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 ☒

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 14:15
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 13:47
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

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 ☒

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 15:33
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3212049

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:55:28

Generated On: 09 Jun 2021 15:46:30

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3212049

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:55:28

Generated On: 09 Jun 2021 15:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212049

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:55:27

Generated On: 09 Jun 2021 15:46:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3212049

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:55:27

Generated On: 09 Jun 2021 15:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212049

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:55:27

Generated On: 09 Jun 2021 15:46:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3212049

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:55:27

Generated On: 09 Jun 2021 15:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212049

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 17:55:58

Generated On: 09 Jun 2021 15:46:30

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

Visit date (dd MMM yyyy)	09 SEP 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 17:55:58

Generated On: 09 Jun 2021 15:46:30

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)	09 SEP 2020
Time of assessment (00:00-23:59)	11:42 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 11:42
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 17:55:58

Generated On: 09 Jun 2021 15:46:30

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)	09 SEP 2020
Time of assessment (00:00-23:59)	13:13 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 13:13
Temperature (xxx.x)	97.8 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)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3212049

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 17:55:58

Generated On: 09 Jun 2021 15:46:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 SEP 2020

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

US3212049

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 17:55:58

Generated On: 09 Jun 2021 15:46:30

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 12:32 (24 HR)

Treatment Date and Time (derived) 09 SEP 2020 12:32

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

US3212049

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 17:55:58

Generated On: 09 Jun 2021 15:46:30

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 09 SEP 2020

Collection time (00:00-23:59) 12:19 (24 HR)

Collection date and time (derived) 09 SEP 2020 12:19

US3212049

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Mar 2021 17:55:58

Generated On: 09 Jun 2021 15:46:30

Collection date (dd MMM yyyy)			09 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:14	09 SEP 2020 12:14
Nasopharyngeal Swab 2	No		

US3212049

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:55:58

Generated On: 09 Jun 2021 15:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

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

97.8 °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

09 SEP 2020 13:12

PC Open Date & Time

09 SEP 2020 12:52

PC Close Date & Time

09 SEP 2020 15:22

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °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	09 SEP 2020 17:20
PC Open Date & Time	09 SEP 2020 16:17
PC Close Date & Time	10 SEP 2020 11:59

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

10 SEP 2020 12:17

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:30

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

98.9 °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

11 SEP 2020 18:55

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 15:23

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 12:21

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:30

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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 14 SEP 2020 12:00

PC Open Date & Time 14 SEP 2020 12:00

PC Close Date & Time 15 SEP 2020 11:59

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

15 SEP 2020 16:07

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 13:12

PC Open Date & Time

09 SEP 2020 12:52

PC Close Date & Time

09 SEP 2020 15:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 17:20

PC Open Date & Time

09 SEP 2020 16:17

PC Close Date & Time

10 SEP 2020 11:59

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:30

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

10 SEP 2020 12:18

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:30

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

11 SEP 2020 18:54

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 15:23

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 12:21

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 12:00

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:30

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

15 SEP 2020 16:07

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 13:13
PC Open Date & Time	09 SEP 2020 12:52
PC Close Date & Time	09 SEP 2020 15:22

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 17:21
PC Open Date & Time	09 SEP 2020 16:17
PC Close Date & Time	10 SEP 2020 11:59

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

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 ☒

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

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

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

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 ☒

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 18:53
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

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

96 of 1899

EAB) (1725)

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 15:23
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

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

98 of 1899

EAB) (1725)

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 12:21
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

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)

100 of 1899

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 12:00
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

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 ☒

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 16:07
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3212049

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:55:28

Generated On: 09 Jun 2021 15:46:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3212049

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:55:27

Generated On: 09 Jun 2021 15:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212049

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:55:28

Generated On: 09 Jun 2021 15:46:30

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3212049

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:55:28

Generated On: 09 Jun 2021 15:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212049

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:55:28

Generated On: 09 Jun 2021 15:46:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3212049

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:55:28

Generated On: 09 Jun 2021 15:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212049

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 17:55:58

Generated On: 09 Jun 2021 15:46:30

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

Visit date (dd MMM yyyy)	06 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT3
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US3212049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 17:55:58

Generated On: 09 Jun 2021 15:46:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	06 OCT 2020
Time of assessment (00:00-23:59)	09:51 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 09:51
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212049

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 17:55:58

Generated On: 09 Jun 2021 15:46:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 OCT 2020

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

US3212049

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 17:55:58

Generated On: 09 Jun 2021 15:46:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	06 OCT 2020
Collection time (00:00-23:59)	10:20 (24 HR)
Collection date and time (derived)	06 OCT 2020 10:20

US3212049

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:55:58

Generated On: 09 Jun 2021 15:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

06 OCT 2020 07:43:03

Patient Cloud Open Date & Time

05 OCT 2020 00:01

Patient Cloud Close Date & Time

09 OCT 2020 23:59

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

12 OCT 2020 10:42:13

Patient Cloud Open Date & Time

12 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 OCT 2020 17:06:55
Patient Cloud Open Date & Time	19 OCT 2020 00:01
Patient Cloud Close Date & Time	23 OCT 2020 23:59

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	02 NOV 2020 10:39:01
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 <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	09 NOV 2020 07:31:23
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 00:02:16

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

20 NOV 2020 09:50:47

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

27 NOV 2020 09:03:49

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

04 DEC 2020 08:33:50

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

11 DEC 2020 08:02:31

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

18 DEC 2020 00:01:38

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

25 DEC 2020 07:24:53

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

01 JAN 2021 09:58:44

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

08 JAN 2021 00:02:16

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 <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	15 JAN 2021 00:01:56
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

22 JAN 2021 10:07:54

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 07:19:50

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 <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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 FEB 2021 06:13:32
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 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	12 FEB 2021 00:02:35
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

19 FEB 2021 08:22:07

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

26 FEB 2021 07:43:30

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

05 MAR 2021 06:02:50

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

12 MAR 2021 13:16:18

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

Date and time of submission

21 MAR 2021 11:08:45

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 07:00:58

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

02 APR 2021 07:25:44

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

09 APR 2021 07:50:59

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

16 APR 2021 07:24:23

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

23 APR 2021 07:02:01

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 00:02:49

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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"/>

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 <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"/>

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 JUL 2021 00:01
Patient Cloud Close Date & Time	06 JUL 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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="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"/>

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01
Patient Cloud Close Date & Time	27 JUL 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

DAY 362

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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°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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

Patient Cloud Open Date & Time	13 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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°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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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°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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 <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"/>

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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"/>

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 <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"/>

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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"/>

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐ 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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 <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"/>

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	07 DEC 2021 23:59
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US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

Date and time of submission	
Patient Cloud Open Date & Time	17 DEC 2021 00:01
Patient Cloud Close Date & Time	21 DEC 2021 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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°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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 <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"/>

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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	21 JAN 2022 00:01
Patient Cloud Close Date & Time	25 JAN 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 <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"/>

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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°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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐ 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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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"/>

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 APR 2022 00:01
Patient Cloud Close Date & Time	26 APR 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐ 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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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°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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

259 of 1899

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 <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"/>

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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"/>

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 <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"/>

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	30 AUG 2022 23:59
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US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	06 SEP 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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	30 SEP 2022 00:01
Patient Cloud Close Date & Time	04 OCT 2022 23:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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="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"/>

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

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

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3212049

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:46:30

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		05 MAR 2021 06:02:38

US3212049

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:55:28

Generated On: 09 Jun 2021 15:46:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 03 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3212049

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:55:28

Generated On: 09 Jun 2021 15:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212049

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 18:00:09

Generated On: 09 Jun 2021 15:46:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212049

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:00:09

Generated On: 09 Jun 2021 15:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212049

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 18:00:09

Generated On: 09 Jun 2021 15:46:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212049

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:00:09

Generated On: 09 Jun 2021 15:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212049

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 18:00:09

Generated On: 09 Jun 2021 15:46:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3212049

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:00:09

Generated On: 09 Jun 2021 15:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212049

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 18:00:09

Generated On: 09 Jun 2021 15:46:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3212049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 18:00:09

Generated On: 09 Jun 2021 15:46:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 FEB 2021
Time of assessment (00:00-23:59)	10:00 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 10:00
Temperature (xxx.x)	97.7 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212049

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 18:00:09

Generated On: 09 Jun 2021 15:46:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 FEB 2021

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

US3212049

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 18:00:09

Generated On: 09 Jun 2021 15:46:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 FEB 2021
Collection time (00:00-23:59)	10:27 (24 HR)
Collection date and time (derived)	24 FEB 2021 10:27

US3212049

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:00:09

Generated On: 09 Jun 2021 15:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212049

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 18:44:24

Generated On: 09 Jun 2021 15:46:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 06 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3212049

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 18:44:24

Generated On: 09 Jun 2021 15:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212049

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

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

US3212049

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3212049

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:46:30

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

US3212049

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:46:30

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3212049

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 18:00:08

Generated On: 09 Jun 2021 15:46:30

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

Visit date (dd MMM yyyy)	14 JAN 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	UNBLND_DECIDE
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US3212049

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 19:24:36

Generated On: 09 Jun 2021 15:46:30

Date of updated informed consent (dd MMM yyyy) 14 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 14 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3212049

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 18:00:08

Generated On: 09 Jun 2021 15:46:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00-23:59)	14:26 (24 HR)
Collection date and time (derived)	14 JAN 2021 14:26

US3212049

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 18:00:08

Generated On: 09 Jun 2021 15:46:30

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

US3212049

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 31 Mar 2021 00:54:14

Generated On: 09 Jun 2021 15:46:30

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

AEID

Adverse event

BILATERAL BACTERIAL
CONJUNCTIVITIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

30 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

320 of 1899

EAB) (1725)

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> 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 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	
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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

AEID	USA-US115-2021-MRNA-1273-P30 1000015
Adverse event	PROSTATE CANCER
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)	01 FEB 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	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	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
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	True
Concomitant Medication	False
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	SUBJECT IS DIAGNOSED WITH PROSTATE CANCER
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)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 18:00:08

Generated On: 09 Jun 2021 15:46:30

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

Yes ☒

No ☐

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

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 18:00:08

Generated On: 09 Jun 2021 15:46:30

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 20

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) 02 Apr 2021 18:00:08

Generated On: 09 Jun 2021 15:46:30

	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)	UN UNK 2010	
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"/>

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 18:00:08

Generated On: 09 Jun 2021 15:46:30

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 20

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 18:00:08

Generated On: 09 Jun 2021 15:46:30

	Intraocular	<input type="checkbox"/>
	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)	UN UNK 2010	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 18:00:08

Generated On: 09 Jun 2021 15:46:30

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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 (3)

Data signed: (b) (4) 02 Apr 2021 18:00:08

Generated On: 09 Jun 2021 15:46:30

	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)	UN UNK 2010	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 18:00:08

Generated On: 09 Jun 2021 15:46:30

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 2000

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 (4)

Data signed: (b) (4) 02 Apr 2021 18:00:08

Generated On: 09 Jun 2021 15:46:30

	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)	UN UNK 2010	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 18:00:08

Generated On: 09 Jun 2021 15:46:30

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 18:00:08

Generated On: 09 Jun 2021 15:46:30

	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)	UN UNK 2010	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 18:00:08

Generated On: 09 Jun 2021 15:46:30

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC HEALTH
PROPHYLAXIS

Dose per administration 81

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 18:00:08

Generated On: 09 Jun 2021 15:46:30

	Intraocular	<input type="checkbox"/>
	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)	UN UNK 2010	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 18:00:08

Generated On: 09 Jun 2021 15:46:30

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication VACCINATION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 18:00:08

Generated On: 09 Jun 2021 15:46:30

	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)		25 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		25 AUG 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 (8)

Data signed: (b) (4) 02 Apr 2021 18:00:08

Generated On: 09 Jun 2021 15:46:30

Name of Medication OFLOXACIN OPHTHALMIC
SOLUTION

Prophylaxis Yes ☐
No ☒

Indication BILATERAL BACTERIAL
CONJUNCTIVITIS

Dose per administration 1

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

If dose unit is Other, specify DROP

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 18:00:08

Generated On: 09 Jun 2021 15:46:30

	Intraocular	<input checked="" type="radio"/>
	Intramuscular	<input 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)		30 NOV 2020
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)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3212049

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 18:00:08

Generated On: 09 Jun 2021 15:46:30

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3212049

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 18:00:08

Generated On: 09 Jun 2021 15:46:30

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
01 FEB 2021	PROSTATE BIOPSY	Other	ELEVATED PSA

US3212049

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:46:30

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

US3212049

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:46:30

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 ☐

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 20 Apr 2021 18:37:24

Generated On: 09 Jun 2021 15:46:30

SAEID	USA-US115-2021-MRNA-1273-P301000015
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input 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)	5

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 20 Apr 2021 18:37:24

Generated On: 09 Jun 2021 15:46:30

SAEID	USA-US115-2021-MRNA-1273-P301000015
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input 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)	5
Date of submission (Pre-filled from custom function)	25/FEB/2021 10:48
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

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 20 Apr 2021 18:37:24

Generated On: 09 Jun 2021 15:46:30

SAEID	USA-US115-2021-MRNA-1273-P301000015
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input 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)	5
Date of submission (Pre-filled from custom function)	08/MAR/2021 09:54
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

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Data signed: (b) (4) 20 Apr 2021 18:37:24

Generated On: 09 Jun 2021 15:46:30

SAEID	USA-US115-2021-MRNA-1273-P301000015
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input 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)	5
Date of submission (Pre-filled from custom function)	09/MAR/2021 14:45
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

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form (4)

Data signed: (b) (4) 20 Apr 2021 18:37:24

Generated On: 09 Jun 2021 15:46:30

SAEID	USA-US115-2021-MRNA-1273-P301000015
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input 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)	5
Date of submission (Pre-filled from custom function)	07/APR/2021 19:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form (5)

Data signed: (b) (4) 20 Apr 2021 18:37:24

Generated On: 09 Jun 2021 15:46:30

SAEID	USA-US115-2021-MRNA-1273-P301000015
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input 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)	5
Date of submission (Pre-filled from custom function)	20/APR/2021 10:25
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

US3212049 (Prod: DM Clinical Research - ERN - PPDS)

US3212049

Form: Participant Creation

Generated On: 09 Jun 2021 15:46:30

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:51:49
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered 'US3212049'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 17:44:21

US3212049

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:46:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:35:00
User entered 'Yes (Y)'	Heather Leary (b) (4)	05 Aug 2020 17:46:07

US3212049

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:35:00
User entered '05 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 17:44:22

US3212049

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:46:30

[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 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:35:00
User entered 'Clinic (Clinic)'	Heather Leary (b) (4)	05 Aug 2020 17:46:07

US3212049

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:46:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered 'SCRN'	System	05 Aug 2020 17:46:07

US3212049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:30

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:21:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:35:22
User entered (b) (6) 1947'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 17:44:23

US3212049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:30

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:21:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:35:22
User entered '72'	Heather Leary (b) (4)	05 Aug 2020 17:47:36

US3212049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:30

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:21:50
User entered 'YEARS'	System	05 Aug 2020 17:47:36

US3212049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:30

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:21:50
User entered '72'	System	05 Aug 2020 17:47:47

US3212049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:30

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:21:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:35:22
User entered 'Male (M)'	Heather Leary (b) (4)	05 Aug 2020 17:47:36

US3212049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:30

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:21:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:35:22
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Heather Leary (b) (4)	05 Aug 2020 17:47:36

US3212049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:30

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:21:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:35:22
User entered 'l'	Heather Leary (b) (4)	05 Aug 2020 17:47:36

US3212049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:30

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:21:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:35:22
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 17:47:36

US3212049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:30

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:21:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:35:22
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 17:47:36

US3212049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:30

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:21:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:35:22
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 17:47:36

US3212049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:30

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:21:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:35:22
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 17:47:36

US3212049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:21:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:35:22
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 17:47:36

US3212049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:30

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:21:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:35:22
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 17:47:36

US3212049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:30

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:21:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:35:22
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 17:47:36

US3212049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:46:30

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:21:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:35:22
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 17:47:36

US3212049

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:30

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:29:15
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:38:02
User entered '05 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:38:02
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:36:06
User entered '5 Aug 2020'	Heather Leary (b) (4)	05 Aug 2020 17:47:47

US3212049

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered 'Aug 2020'	System	05 Aug 2020 17:47:47

US3212049

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered '2020'	System	05 Aug 2020 17:47:47

US3212049

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:30

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:36:06
User entered 'Amendment 1 (1)'	Heather Leary (b) (4)	05 Aug 2020 17:47:47

US3212049

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:36:06
User entered 'Yes (Y)'	Heather Leary (b) (4)	05 Aug 2020 17:47:47

US3212049

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:36:06
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 17:47:47

US3212049

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:30

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:36:06
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 17:47:47

US3212049

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:30

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:36:06
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:47:47

US3212049

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:30

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:36:06
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 17:44:22

US3212049

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:46:30

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered 'I'	System	05 Aug 2020 17:47:54

US3212049

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:36:54
User entered 'Yes (Y)'	Heather Leary (b) (4)	05 Aug 2020 17:47:54

US3212049

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:46:30

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:37:38
User entered 'Yes (Y)'	Heather Leary (b) (4)	05 Aug 2020 17:48:13

US3212049

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:46:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:12
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 17:51:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 17:51:00
Data point term sent to Coder	System	05 Aug 2020 17:49:22
User entered 'Hypertension'	Heather Leary (b) (4)	05 Aug 2020 17:49:07

US3212049

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:12
User entered 'un UNK 2010'	Heather Leary (b) (4)	05 Aug 2020 17:49:07

US3212049

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:12
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 17:49:07

US3212049

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:46:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:12
User entered 'Yes (Y)'	Heather Leary (b) (4)	05 Aug 2020 17:49:07

US3212049

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:12
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 17:49:07

US3212049

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:46:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:12
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 17:49:07

US3212049

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered 'Jan 2010'	System	05 Aug 2020 17:49:07

US3212049

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered '2010'	System	05 Aug 2020 17:49:07

US3212049

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered empty.	System	05 Aug 2020 17:49:07

US3212049

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered empty.	System	05 Aug 2020 17:49:07

US3212049

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:12
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 17:51:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 17:51:01
Data point term sent to Coder	System	05 Aug 2020 17:50:22
User entered 'Hypercholesterolemia'	Heather Leary (b) (4)	05 Aug 2020 17:49:34

US3212049

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:12
User entered 'UN UNK 2010'	Heather Leary (b) (4)	05 Aug 2020 17:49:34

US3212049

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:12
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 17:49:34

US3212049

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:12
User entered 'Yes (Y)'	Heather Leary (b) (4)	05 Aug 2020 17:49:34

US3212049

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:12
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 17:49:34

US3212049

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:12
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 17:49:34

US3212049

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered 'Jan 2010'	System	05 Aug 2020 17:49:34

US3212049

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered '2010'	System	05 Aug 2020 17:49:34

US3212049

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered empty.	System	05 Aug 2020 17:49:34

US3212049

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered empty.	System	05 Aug 2020 17:49:34

US3212049

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:46:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:12
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 17:51:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 17:51:01
Data point term sent to Coder	System	05 Aug 2020 17:50:22
User entered 'Gastroesophageal reflux disease'	Heather Leary (b) (4)	05 Aug 2020 17:50:02

US3212049

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:12
User entered 'un UNK 2010'	Heather Leary (b) (4)	05 Aug 2020 17:50:02

US3212049

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:12
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 17:50:02

US3212049

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:46:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:12
User entered 'Yes (Y)'	Heather Leary (b) (4)	05 Aug 2020 17:50:02

US3212049

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:12
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 17:50:02

US3212049

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:46:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:12
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 17:50:02

US3212049

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered 'Jan 2010'	System	05 Aug 2020 17:50:02

US3212049

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered '2010'	System	05 Aug 2020 17:50:02

US3212049

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered empty.	System	05 Aug 2020 17:50:02

US3212049

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered empty.	System	05 Aug 2020 17:50:02

US3212049

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:46:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:32:01
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
User closed query 'Per DM CLR: Please update the condition to confirm if the STOMACH TUMOR was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 12:06:52
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms malignant and unspecified, HLT: Gastric neoplasms malignant, PT: Gastric cancer, LLT: Stomach cancer - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 07:02:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 07:02:52
Data point term sent to Coder	System	25 Sep 2020 19:34:56
Query 'Per DM CLR: Please update the condition to confirm if the STOMACH TUMOR was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4) (b) (4)	25 Sep 2020 19:34:56
DataPoint Un-verified.	Afifah Ayub (b) (4) (b) (4)	25 Sep 2020 19:34:51
Coding entries removed.	Afifah Ayub (b) (4) (b) (4)	25 Sep 2020 19:34:51
User entered 'cancerous STOMACH TUMOR' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	25 Sep 2020 19:34:51
User opened query 'Per DM CLR: Please update the condition to confirm if the STOMACH TUMOR was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 14:13:35
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:12

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:46:30

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Miscellaneous and site unspecified neoplasms malignant and unspecified, HLT: Neoplasms unspecified malignancy and site unspecified NEC, PT: Abdominal neoplasm, LLT: Abdominal tumor - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 06:51:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 06:51:16
Data point term sent to Coder	System	05 Aug 2020 17:50:25
User entered 'Stomach tumor'	Heather Leary (b) (4)	05 Aug 2020 17:50:24

US3212049

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:12
User entered 'un UNK 2010'	Heather Leary (b) (4)	05 Aug 2020 17:50:24

US3212049

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:12
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 17:50:24

US3212049

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:46:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:12
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:50:24

US3212049

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:12
User entered 'un UNK 2010'	Heather Leary (b) (4)	05 Aug 2020 17:50:24

US3212049

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:46:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:12
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 17:50:24

US3212049

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered 'Jan 2010'	System	05 Aug 2020 17:50:24

US3212049

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered '2010'	System	05 Aug 2020 17:50:24

US3212049

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered 'Jan 2010'	System	05 Aug 2020 17:50:24

US3212049

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered '2010'	System	05 Aug 2020 17:50:24

US3212049

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:46:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:33:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 21:18:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 21:18:18
Data point term sent to Coder	System	17 Aug 2020 21:16:59
User entered 'Obesity'	Heather Leary (b) (4)	17 Aug 2020 21:16:55

US3212049

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:51:38
User closed query 'Per source, condition started 00-000-2020. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 17:29:04
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:28:49
Query 'Per source, condition started 00-000-2020. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Jagruti Patel (b) (4)	05 Apr 2021 16:26:17
Signature has been broken.	Jagruti Patel (b) (4)	05 Apr 2021 16:26:02
User entered 'UN UNK 2020' reason for change: Data Entry Error	Jagruti Patel (b) (4)	05 Apr 2021 16:26:02
User opened query 'Per source, condition started 00-000-2020. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	03 Apr 2021 21:33:05
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
User closed query 'Per CDM: Start date is the same as the Informed Consent date? Diseases/conditions that are deemed relevant/ significant which started prior to Informed Consent should be only recorded on the Medical History form. Please review and update accordingly or, state otherwise.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 11:24:57
Query 'Per CDM: Start date is the same as the Informed Consent date? Diseases/conditions that are deemed relevant/ significant which started prior to Informed Consent should be only recorded on the Medical History form. Please review and update accordingly or, state otherwise.' answered with 'updated per subject' (Site from DM).	Reagan Reed (b) (4)	19 Nov 2020 15:57:50
User entered 'UN UNK 2010' reason for change: Data Entry Error	Reagan Reed (b) (4)	19 Nov 2020 15:57:41

US3212049

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per CDM: Start date is the same as the Informed Consent date? Diseases/conditions that are deemed relevant/ significant which started prior to Informed Consent should be only recorded on the Medical History form. Please review and update accordingly or, state otherwise.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 10:33:21
Query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day? Please review and update as per page 24 of the CCGs. Thank you' canceled (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 10:32:53
User opened query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day? Please review and update as per page 24 of the CCGs. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 10:32:17
User entered '05 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	24 Aug 2020 14:36:26
User entered empty.	Heather Leary (b) (4)	17 Aug 2020 21:16:55

US3212049

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:33:09
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
User entered '0' reason for change: Data Entry Error	Atifah Ayub (b) (4)	24 Aug 2020 14:36:26
User entered '1'	Heather Leary (b) (4)	17 Aug 2020 21:16:55

US3212049

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:46:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:33:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 21:17:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 21:17:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Leary (b) (4)	17 Aug 2020 21:17:00
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 21:16:55
User entered empty.	Heather Leary (b) (4)	17 Aug 2020 21:16:55

US3212049

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:33:20
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
User entered empty.	Heather Leary (b) (4)	17 Aug 2020 21:16:55

US3212049

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:46:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:33:24
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
User entered '0'	Heather Leary (b) (4)	17 Aug 2020 21:16:55

US3212049

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered 'Jan 2020'	System	05 Apr 2021 16:26:02
User entered 'Jan 2010'	System	19 Nov 2020 15:57:41
User entered 'Aug 2020'	System	24 Aug 2020 14:36:26
User entered empty.	System	17 Aug 2020 21:16:55

US3212049

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered '2020'	System	05 Apr 2021 16:26:02
User entered '2010'	System	19 Nov 2020 15:57:41
User entered '2020'	System	24 Aug 2020 14:36:26
User entered empty.	System	17 Aug 2020 21:16:55

US3212049

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered empty.	System	17 Aug 2020 21:16:55

US3212049

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered empty.	System	17 Aug 2020 21:16:55

US3212049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:18
User entered 'Yes (Y)'	Heather Leary (b) (4)	05 Aug 2020 17:51:28

US3212049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:31:23
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:38:16
User entered '05 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:38:16
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:20
User entered '5 Aug 2020'	Heather Leary (b) (4)	05 Aug 2020 17:51:28

US3212049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:22
User entered '12:00'	Heather Leary (b) (4)	05 Aug 2020 17:51:28

US3212049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered '05 Aug 2020 12:00'	System	02 Dec 2020 20:38:16
User entered '5 Aug 2020 12:00'	System	05 Aug 2020 17:51:28

US3212049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:31
User entered '75' in	Heather Leary (b) (4)	05 Aug 2020 17:51:28
DataPoint set to visible.	System	05 Aug 2020 17:47:54

US3212049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:39:33
User entered '293' lb	Heather Leary (b) (4)	05 Aug 2020 17:51:28
DataPoint set to visible.	System	05 Aug 2020 17:47:54

US3212049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
Amendment Manager: User entered '36.69906'	System	16 Sep 2020 23:44:14
User entered '36.7'	System	05 Aug 2020 17:51:28
DataPoint set to visible.	System	05 Aug 2020 17:47:54

US3212049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered 'kg/m2'	System	05 Aug 2020 17:51:28
DataPoint set to visible.	System	05 Aug 2020 17:47:54

US3212049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:08:39
User closed query 'Remove vitals except height and weight and mark 'ND'.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 19:08:31
Query 'Remove vitals except height and weight and mark 'ND'.' answered with 'updated' (Site from CRA).	Heather Leary (b) (4)	17 Aug 2020 21:18:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Leary (b) (4)	17 Aug 2020 21:17:59
User opened query 'Remove vitals except height and weight and mark 'ND'.' (Site from CRA).	(b) (4), (b) (6)	14 Aug 2020 19:40:01
User entered '97.2' F	Heather Leary (b) (4)	05 Aug 2020 17:51:28

US3212049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:08:39
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 17:10:48
User entered 'Other (Other)' reason for change: Data Entry Error	Heather Leary (b) (4)	17 Aug 2020 21:17:59
User entered 'Oral (Oral)'	Heather Leary (b) (4)	05 Aug 2020 17:51:28

US3212049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:08:39
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 17:10:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Leary (b) (4)	17 Aug 2020 21:17:59
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 17:51:28

US3212049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:08:39
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Leary (b) (4)	17 Aug 2020 21:17:59
User entered '64'	Heather Leary (b) (4)	05 Aug 2020 17:51:28

US3212049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered 'bpm'	System	05 Aug 2020 17:51:28

US3212049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:08:39
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Leary (b) (4)	17 Aug 2020 21:17:59
User entered '14'	Heather Leary (b) (4)	05 Aug 2020 17:51:28

US3212049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered 'breaths/min'	System	05 Aug 2020 17:51:28

US3212049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:08:39
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Leary (b) (4)	17 Aug 2020 21:17:59
User entered '139'	Heather Leary (b) (4)	05 Aug 2020 17:51:28

US3212049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered 'mmHg'	System	05 Aug 2020 17:51:28

US3212049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:08:39
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Leary (b) (4)	17 Aug 2020 21:17:59
User entered '84'	Heather Leary (b) (4)	05 Aug 2020 17:51:28

US3212049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User entered 'mmHg'	System	05 Aug 2020 17:51:28

US3212049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06

US3212049

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:30

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
User closed query 'Add obesity to MH, per PE finding in source.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 19:08:08
Query 'Add obesity to MH, per PE finding in source.' answered with 'Updated' (Site from CRA).	Heather Leary (b) (4)	17 Aug 2020 21:17:13
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:42:32
User opened query 'Add obesity to MH, per PE finding in source.' (Site from CRA).	(b) (4), (b) (6)	14 Aug 2020 19:41:35
User entered 'Yes (Y)'	Heather Leary (b) (4)	05 Aug 2020 17:52:18

US3212049

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:30:23
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:38:23
User entered '05 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:38:23
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 13:44:59
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		09 Sep 2020 17:38:41
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:42:32
User entered '5 Aug 2020'	Heather Leary (b) (4)	05 Aug 2020 17:52:18

US3212049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:30

[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 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:43:18
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:53:27

US3212049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:30

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 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:43:18
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:53:27

US3212049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:30

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 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:43:18
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:53:27

US3212049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:30

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 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:43:18
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:53:27

US3212049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:30

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 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:43:18
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:53:27

US3212049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:30

[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 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:43:18
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:53:27

US3212049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:30

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 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:43:18
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:53:27

US3212049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:30

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 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:43:18
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:53:27

US3212049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:30

[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 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:43:18
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:53:27

US3212049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:30

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 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:43:18
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:53:27

US3212049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:30

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 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:43:18
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:53:27

US3212049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:30

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:43:18
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:53:27

US3212049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:30

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:43:18
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 17:53:27

US3212049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:30

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 17:53:27

US3212049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:30

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:43:18
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 17:53:27

US3212049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:30

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 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:43:18
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 17:53:27

US3212049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:30

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 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:43:18
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 17:53:27

US3212049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:30

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 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:43:18
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 17:53:27

US3212049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:43:18
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 17:53:27

US3212049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:30

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
User entered 'I'	Heather Leary (b) (4)	05 Aug 2020 17:53:27

US3212049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:46:30

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:23:06
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:43:18
User entered 'goes to place of worship once a week, goes to the store 2+/week, attends gatherings of 10 people more than 2 times a month, eats out at restaurants 1+/week'	Heather Leary (b) (4)	05 Aug 2020 17:53:27

US3212049

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:46:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:44:19
User entered 'Yes (Y)'	Heather Leary (b) (4)	05 Aug 2020 17:54:00

US3212049

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:29:34
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Un-verified.	Afifah Ayub (b) (4)	10 Nov 2020 15:10:31
User entered '05 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	10 Nov 2020 15:10:31
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:44:19
User entered '5 Aug 2020'	Heather Leary (b) (4)	05 Aug 2020 17:54:00

US3212049

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:46:30

[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 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:44:19
User entered 'Clinic (Clinic)'	Heather Leary (b) (4)	05 Aug 2020 17:54:00

US3212049

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:46:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'VISIT1'	System	05 Aug 2020 17:54:00

US3212049

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:44:40
User entered '05 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 17:44:30

US3212049

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:30

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:17:33
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:17:32
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:44:40
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Aug 2020 17:44:30
User entered '184752' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 17:44:30

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:44:40
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 17:44:30

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:30

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 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:44:40
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:54:27

US3212049

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:30

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 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:44:40
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:54:27

US3212049

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:44:40
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:54:27

US3212049

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:30

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:44:40
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:54:27

US3212049

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:46:30

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:44:40
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:54:27

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:46:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:40:13
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:46:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:40:15
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:46:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:40:13
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:46:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:40:15
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User accepted default value 'Pre-Dose (PREDOSE)'	Afifah Ayub (b) (4) (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:40:20
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:30:36
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:38:43
User entered '05 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:38:43
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:40:22
User entered '5 Aug 2020'	Afifah Ayub (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:40:23
User entered '12:00'	Afifah Ayub (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered '05 Aug 2020 12:00'	System	02 Dec 2020 20:38:43
User entered '5 Aug 2020 12:00'	System	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:40:26
User entered '97.2' F	Afifah Ayub (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:40:27
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:40:29
User entered empty.	Afifah Ayub (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:40:31
User entered '64'	Afifah Ayub (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'bpm'	System	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:40:35
User entered '14'	Afifah Ayub (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'breaths/min'	System	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:40:39
User entered '139'	Afifah Ayub (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'mmHg'	System	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:40:41
User entered '84'	Afifah Ayub (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'mmHg'	System	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:46:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:40:13
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:46:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:40:15
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User accepted default value 'Post-Dose (POSTDOSE)'	Afifah Ayub (b) (4) (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:45:51
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:30:46
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:38:43
User entered '05 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:38:43
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:45:53
User entered '5 Aug 2020'	Afifah Ayub (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:45:56
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)	06 Aug 2020 18:13:09
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)	05 Aug 2020 19:22:37
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		05 Aug 2020 19:22:23
User entered '14:13'	Afifah Ayub (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered '05 Aug 2020 14:13'	System	02 Dec 2020 20:38:43
User entered '5 Aug 2020 14:13'	System	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
User closed query 'Per source, Temperature is 96.6. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 19:09:14
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 19:09:01
User closed query 'Per CDM: Please Indicate CS or NCS' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 16:57:30
Query 'Per CDM: Please Indicate CS or NCS' answered with 'NCS' (Site from DM).	Afifah Ayub (b) (4)	13 Oct 2020 16:49:22
User opened query 'Per CDM: Please Indicate CS or NCS' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:55:42
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)	13 Oct 2020 10:49:28
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 19:05:51
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 23:44:14
Query 'Per source, Temperature is 96.6. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Heather Leary (b) (4)	17 Aug 2020 21:19:12
User entered '96.6' F reason for change: Data Entry Error	Heather Leary (b) (4)	17 Aug 2020 21:19:06
User opened query 'Per source, Temperature is 96.6. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Aug 2020 19:46:35
DataPoint Un-verified.	(b) (4), (b) (6)	14 Aug 2020 19:46:02

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:45:59
User entered '96.9' F	Afifah Ayub (b) (4) (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:46:38
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:46:39
User entered empty.	Afifah Ayub (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:46:41
User entered '59'	Afifah Ayub (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'bpm'	System	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:46:44
User entered '16'	Afifah Ayub (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'breaths/min'	System	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:46:47
User entered '148'	Afifah Ayub (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'mmHg'	System	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:46:49
User entered '86'	Afifah Ayub (b) (4)	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'mmHg'	System	05 Aug 2020 19:22:23

US3212049

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:46:56
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:54:45

US3212049

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:46:56
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 17:54:45

US3212049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:46:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:47:17
User entered 'Yes (Y)'	Heather Leary (b) (4)	05 Aug 2020 18:40:59

US3212049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:46:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:47:17
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 18:40:59

US3212049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:46:30

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 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:47:17
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 18:40:59

US3212049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:46:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'MRNA-1273 OR PLACEBO'	System	05 Aug 2020 18:40:59

US3212049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:46:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:30:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:38:54
User entered '05 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:38:54
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:47:17
User entered '5 Aug 2020'	Heather Leary (b) (4)	05 Aug 2020 18:40:59

US3212049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:47:17
User entered '13:16'	Heather Leary (b) (4)	05 Aug 2020 18:40:59

US3212049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered '05 Aug 2020 13:16'	System	02 Dec 2020 20:38:54
User entered '5 Aug 2020 13:16'	System	05 Aug 2020 18:40:59

US3212049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:47:17
User entered 'Left Arm (LEFT ARM)'	Heather Leary (b) (4)	05 Aug 2020 18:40:59

US3212049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:47:17
User entered 'ONCE'	System	05 Aug 2020 18:40:59

US3212049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'INTRAMUSCULAR'	System	05 Aug 2020 18:40:59

US3212049

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:47:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	05 Aug 2020 18:43:48

US3212049

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:29:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:39:03
User entered '05 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:39:03
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:47:33
User entered '5 Aug 2020'	Afifah Ayub (b) (4)	05 Aug 2020 18:43:48

US3212049

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:47:33
User entered '13:05'	Afifah Ayub (b) (4)	05 Aug 2020 18:43:48

US3212049

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered '05 Aug 2020 13:05'	System	02 Dec 2020 20:39:03
User entered '5 Aug 2020 13:05'	System	05 Aug 2020 18:43:48

US3212049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:46:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:30:10
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:39:10
User entered '05 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:39:10
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:47:42
User entered '5 Aug 2020'	Afifah Ayub (b) (4)	05 Aug 2020 18:44:15

US3212049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:46:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Afifah Ayub (b) (4) (b) (4)	05 Aug 2020 18:44:15

US3212049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:46:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:47:42
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	05 Aug 2020 18:44:15

US3212049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:47:42
User entered '12:58'	Afifah Ayub (b) (4)	05 Aug 2020 18:44:15

US3212049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered '05 Aug 2020 12:58'	System	02 Dec 2020 20:39:10
User entered '5 Aug 2020 12:58'	System	05 Aug 2020 18:44:15

US3212049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:46:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Afifah Ayub (b) (4)	05 Aug 2020 18:44:15

US3212049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:46:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:30:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	25 Aug 2020 20:10:44
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Aug 2020 20:10:44
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:47:42
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	05 Aug 2020 18:44:15

US3212049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:46:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:30:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	25 Aug 2020 20:10:44
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Aug 2020 20:10:44
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 19:47:42
User entered '12:58'	Afifah Ayub (b) (4)	05 Aug 2020 18:44:15

US3212049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered empty.	System	25 Aug 2020 20:10:44
User entered '5 Aug 2020 12:58'	System	05 Aug 2020 18:44:15

US3212049

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:29:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	18 Aug 2020 19:52:14

US3212049

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'I'	System	18 Aug 2020 19:52:14

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T13:49:05', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'fff3a135-8fd0-476d-8946-3ad69e6622d4' User entered 'Yes (Y)'	System	05 Aug 2020 18:49:31
	System	05 Aug 2020 18:49:31

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T13:49:13', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'fff3a135-8fd0-476d-8946-3ad69e6622d4'	System	05 Aug 2020 18:49:31
User entered '96.6'	System	05 Aug 2020 18:49:31

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T13:49:21', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'fff3a135-8fd0-476d-8946-3ad69e6622d4'	System	05 Aug 2020 18:49:31
User entered 'No (N)'	System	05 Aug 2020 18:49:31

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T13:49:30', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'fff3a135-8fd0-476d-8946-3ad69e6622d4'	System	05 Aug 2020 18:49:31
User entered '05 Aug 2020 13:49'	System	05 Aug 2020 18:49:31

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '05 Aug 2020 13:36'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '05 Aug 2020 16:06'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T18:20:47', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '8d1688b4-ecb6-4b40-9d35-2495cb5aa4a5' User entered 'Yes (Y)'	System	05 Aug 2020 23:21:09
	System	05 Aug 2020 23:21:09

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T18:21:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '8d1688b4-ecb6-4b40-9d35-2495cb5aa4a5' User entered '98.9'	System	05 Aug 2020 23:21:09
	System	05 Aug 2020 23:21:09

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T18:21:04', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '8d1688b4-ecb6-4b40-9d35-2495cb5aa4a5' User entered 'No (N)'	System	05 Aug 2020 23:21:09
	System	05 Aug 2020 23:21:09

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T18:21:08', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '8d1688b4-ecb6-4b40-9d35-2495cb5aa4a5' User entered '05 Aug 2020 18:21'	System	05 Aug 2020 23:21:09
	System	05 Aug 2020 23:21:09

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '05 Aug 2020 17:01'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 2'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:30

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-06T13:25:10', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3c8d835b-9a74-41b4-a50a-eea42eb2717f' User entered 'Yes (Y)'	System	06 Aug 2020 18:25:27
	System	06 Aug 2020 18:25:27

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:30

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-06T13:25:15', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3c8d835b-9a74-41b4-a50a-eea42eb2717f' User entered '97.9'	System	06 Aug 2020 18:25:27
	System	06 Aug 2020 18:25:27

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-06T13:25:20', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3c8d835b-9a74-41b4-a50a-eea42eb2717f' User entered 'No (N)'	System	06 Aug 2020 18:25:27
	System	06 Aug 2020 18:25:27

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-06T13:25:25', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3c8d835b-9a74-41b4-a50a-eea42eb2717f' User entered '06 Aug 2020 13:25'	System	06 Aug 2020 18:25:27
	System	06 Aug 2020 18:25:27

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 3'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:30

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-07T14:20:25', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '977db86a-0c78-45cf-b11d-2993f5f62658' User entered 'Yes (Y)'	System	07 Aug 2020 19:20:41
	System	07 Aug 2020 19:20:41

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-07T14:20:30', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '977db86a-0c78-45cf-b11d-2993f5f62658' User entered '98.1'	System	07 Aug 2020 19:20:41
	System	07 Aug 2020 19:20:41

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-07T14:20:33', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '977db86a-0c78-45cf-b11d-2993f5f62658' User entered 'No (N)'	System	07 Aug 2020 19:20:41
	System	07 Aug 2020 19:20:41

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-07T14:20:38', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '977db86a-0c78-45cf-b11d-2993f5f62658' User entered '07 Aug 2020 14:20'	System	07 Aug 2020 19:20:41
	System	07 Aug 2020 19:20:41

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 4'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:30

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-08T14:01:17', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '1942846d-129c-4fe7-ba8e-bd9c1c2fa6e1' User entered 'Yes (Y)'	System	08 Aug 2020 19:01:30
	System	08 Aug 2020 19:01:30

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-08T14:01:23', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '1942846d-129c-4fe7-ba8e-bd9c1c2fa6e1' User entered '98.2'	System	08 Aug 2020 19:01:30
	System	08 Aug 2020 19:01:30

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-08T14:01:25', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '1942846d-129c-4fe7-ba8e-bd9c1c2fa6e1' User entered 'No (N)'	System	08 Aug 2020 19:01:30
	System	08 Aug 2020 19:01:30

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-08T14:01:27', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '1942846d-129c-4fe7-ba8e-bd9c1c2fa6e1' User entered '08 Aug 2020 14:01'	System	08 Aug 2020 19:01:30
	System	08 Aug 2020 19:01:30

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 5'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:30

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-09T14:14:58', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '2b020684-447b-4c08-9417-3f42ff1f357a' User entered 'Yes (Y)'	System	09 Aug 2020 19:15:12
	System	09 Aug 2020 19:15:12

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-09T14:15:06', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '2b020684-447b-4c08-9417-3f42ff1f357a' User entered '97.4'	System	09 Aug 2020 19:15:12
	System	09 Aug 2020 19:15:12

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-09T14:15:08', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '2b020684-447b-4c08-9417-3f42ff1f357a' User entered 'No (N)'	System	09 Aug 2020 19:15:12
	System	09 Aug 2020 19:15:12

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-09T14:15:10', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '2b020684-447b-4c08-9417-3f42ff1f357a'	System	09 Aug 2020 19:15:12
User entered '09 Aug 2020 14:15'	System	09 Aug 2020 19:15:12

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 6'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:30

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-10T13:46:56', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '9f526105-1f02-4987-9c6d-3f3197b7bbd6' User entered 'Yes (Y)'	System	10 Aug 2020 18:47:11
	System	10 Aug 2020 18:47:11

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:30

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-10T13:47:02', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '9f526105-1f02-4987-9c6d-3f3197b7bbd6' User entered '97.7'	System	10 Aug 2020 18:47:11
	System	10 Aug 2020 18:47:11

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-10T13:47:06', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '9f526105-1f02-4987-9c6d-3f3197b7bbd6'	System	10 Aug 2020 18:47:11
User entered 'No (N)'	System	10 Aug 2020 18:47:11

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-10T13:47:09', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '9f526105-1f02-4987-9c6d-3f3197b7bbd6' User entered '10 Aug 2020 13:47'	System	10 Aug 2020 18:47:11
	System	10 Aug 2020 18:47:11

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 7'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:30

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-11T15:33:28', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '4c5b9746-0b93-4c3b-a42b-6227c23cd45a' User entered 'Yes (Y)'	System	11 Aug 2020 20:34:07
	System	11 Aug 2020 20:34:07

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:30

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-11T15:33:54', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '4c5b9746-0b93-4c3b-a42b-6227c23cd45a' User entered '97.7'	System	11 Aug 2020 20:34:07
	System	11 Aug 2020 20:34:07

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-11T15:33:59', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '4c5b9746-0b93-4c3b-a42b-6227c23cd45a' User entered 'No (N)'	System	11 Aug 2020 20:34:07
	System	11 Aug 2020 20:34:07

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-11T15:34:03', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '4c5b9746-0b93-4c3b-a42b-6227c23cd45a' User entered '11 Aug 2020 15:34'	System	11 Aug 2020 20:34:07
	System	11 Aug 2020 20:34:07

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T13:49:42', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '95107328-72b6-4888-ae51-a8732d507b04'	System	05 Aug 2020 18:50:37
User entered 'None (1)'	System	05 Aug 2020 18:50:37

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T13:49:59', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '95107328-72b6-4888-ae51-a8732d507b04'	System	05 Aug 2020 18:50:37
User entered 'Yes (Y)'	System	05 Aug 2020 18:50:37

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T13:50:23', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '95107328-72b6-4888-ae51-a8732d507b04' User entered '1'	System	05 Aug 2020 18:50:37
	System	05 Aug 2020 18:50:37

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T13:50:27', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '95107328-72b6-4888-ae51-a8732d507b04'	System	05 Aug 2020 18:50:37
User entered 'No (N)'	System	05 Aug 2020 18:50:37

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T13:50:30', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '95107328-72b6-4888-ae51-a8732d507b04' User entered 'None (1)'	System	05 Aug 2020 18:50:37
	System	05 Aug 2020 18:50:37

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T13:50:33', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '95107328-72b6-4888-ae51-a8732d507b04'	System	05 Aug 2020 18:50:37
User entered '05 Aug 2020 13:50'	System	05 Aug 2020 18:50:37

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '05 Aug 2020 13:36'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '05 Aug 2020 16:06'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T18:22:29', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '8705663c-8327-4c9d-bcb7-beb7c0979263' User entered 'None (1)'	System	05 Aug 2020 23:22:53
	System	05 Aug 2020 23:22:53

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T18:22:34', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '8705663c-8327-4c9d-bcb7-beb7c0979263' User entered 'No (N)'	System	05 Aug 2020 23:22:53
	System	05 Aug 2020 23:22:53

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T18:22:38', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '8705663c-8327-4c9d-bcb7-beb7c0979263' User entered 'No (N)'	System	05 Aug 2020 23:22:53
	System	05 Aug 2020 23:22:53

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T18:22:46', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '8705663c-8327-4c9d-bcb7-beb7c0979263' User entered 'None (1)'	System	05 Aug 2020 23:22:53
	System	05 Aug 2020 23:22:53

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T18:22:49', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '8705663c-8327-4c9d-bcb7-beb7c0979263' User entered '05 Aug 2020 18:22'	System	05 Aug 2020 23:22:53
	System	05 Aug 2020 23:22:53

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '05 Aug 2020 17:01'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 2'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-06T13:21:24', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '66690fa7-fbb2-429b-babf-ed06d7640abb' User entered 'Does not interfere with activity (2)'	System	06 Aug 2020 18:22:06
	System	06 Aug 2020 18:22:06

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-06T13:21:40', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '66690fa7-fbb2-429b-babf-ed06d7640abb' User entered 'No (N)'	System	06 Aug 2020 18:22:06
	System	06 Aug 2020 18:22:06

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-06T13:21:51', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '66690fa7-fbb2-429b-babf-ed06d7640abb' User entered 'No (N)'	System	06 Aug 2020 18:22:06
	System	06 Aug 2020 18:22:06

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-06T13:21:56', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '66690fa7-fbb2-429b-babf-ed06d7640abb' User entered 'None (1)'	System	06 Aug 2020 18:22:06
	System	06 Aug 2020 18:22:06

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-06T13:22:03', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '66690fa7-fbb2-429b-babf-ed06d7640abb' User entered '06 Aug 2020 13:22'	System	06 Aug 2020 18:22:06
	System	06 Aug 2020 18:22:06

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 3'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-07T14:19:20', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '2737ef74-cf39-44c3-9d22-cbd39f9eb143'	System	07 Aug 2020 19:20:22
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 19:20:22

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-07T14:19:23', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '2737ef74-cf39-44c3-9d22-cbd39f9eb143'	System	07 Aug 2020 19:20:22
User entered 'No (N)'	System	07 Aug 2020 19:20:22

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-07T14:19:29', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '2737ef74-cf39-44c3-9d22-cbd39f9eb143'	System	07 Aug 2020 19:20:22
User entered 'No (N)'	System	07 Aug 2020 19:20:22

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-07T14:20:16', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '2737ef74-cf39-44c3-9d22-cbd39f9eb143'	System	07 Aug 2020 19:20:22
User entered 'None (1)'	System	07 Aug 2020 19:20:22

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-07T14:20:19', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '2737ef74-cf39-44c3-9d22-cbd39f9eb143' User entered '07 Aug 2020 14:20'	System	07 Aug 2020 19:20:22
	System	07 Aug 2020 19:20:22

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 4'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:30

Please record - PAIN AT INJECTION SITE.

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-08T14:01:31', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'fad008ea-8338-436a-8752-160552ee59c9'	System	08 Aug 2020 19:01:46
User entered 'None (1)'	System	08 Aug 2020 19:01:46

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-08T14:01:36', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'fad008ea-8338-436a-8752-160552ee59c9'	System	08 Aug 2020 19:01:46
User entered 'No (N)'	System	08 Aug 2020 19:01:46

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-08T14:01:38', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'fad008ea-8338-436a-8752-160552ee59c9'	System	08 Aug 2020 19:01:46
User entered 'No (N)'	System	08 Aug 2020 19:01:46

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-08T14:01:41', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'fad008ea-8338-436a-8752-160552ee59c9' User entered 'None (1)'	System	08 Aug 2020 19:01:46
	System	08 Aug 2020 19:01:46

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-08T14:01:44', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'fad008ea-8338-436a-8752-160552ee59c9' User entered '08 Aug 2020 14:01'	System	08 Aug 2020 19:01:46
	System	08 Aug 2020 19:01:46

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 5'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-09T14:15:13', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '64108490-dd0d-4e0d-8b80-60b537ad9ec8'	System	09 Aug 2020 19:15:25
User entered 'None (1)'	System	09 Aug 2020 19:15:25

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-09T14:15:17', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '64108490-dd0d-4e0d-8b80-60b537ad9ec8'	System	09 Aug 2020 19:15:25
User entered 'No (N)'	System	09 Aug 2020 19:15:25

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-09T14:15:19', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '64108490-dd0d-4e0d-8b80-60b537ad9ec8'	System	09 Aug 2020 19:15:25
User entered 'No (N)'	System	09 Aug 2020 19:15:25

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-09T14:15:21', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '64108490-dd0d-4e0d-8b80-60b537ad9ec8'	System	09 Aug 2020 19:15:25
User entered 'None (1)'	System	09 Aug 2020 19:15:25

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-09T14:15:23', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '64108490-dd0d-4e0d-8b80-60b537ad9ec8' User entered '09 Aug 2020 14:15'	System	09 Aug 2020 19:15:25
	System	09 Aug 2020 19:15:25

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 6'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-10T13:47:17', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '588d38cf-7f8a-4b55-914a-a41b2c6731e5' User entered 'None (1)'	System	10 Aug 2020 18:47:29
	System	10 Aug 2020 18:47:29

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-10T13:47:19', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '588d38cf-7f8a-4b55-914a-a41b2c6731e5' User entered 'No (N)'	System	10 Aug 2020 18:47:29
	System	10 Aug 2020 18:47:29

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-10T13:47:21', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '588d38cf-7f8a-4b55-914a-a41b2c6731e5' User entered 'No (N)'	System	10 Aug 2020 18:47:29
	System	10 Aug 2020 18:47:29

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-10T13:47:25', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '588d38cf-7f8a-4b55-914a-a41b2c6731e5' User entered 'None (1)'	System	10 Aug 2020 18:47:29
	System	10 Aug 2020 18:47:29

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-10T13:47:27', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '588d38cf-7f8a-4b55-914a-a41b2c6731e5' User entered '10 Aug 2020 13:47'	System	10 Aug 2020 18:47:29
	System	10 Aug 2020 18:47:29

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 7'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-11T15:33:13', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3b596827-3989-4719-a236-9b8e53eb0f35'	System	11 Aug 2020 20:33:25
User entered 'None (1)'	System	11 Aug 2020 20:33:25

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-11T15:33:16', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3b596827-3989-4719-a236-9b8e53eb0f35'	System	11 Aug 2020 20:33:25
User entered 'No (N)'	System	11 Aug 2020 20:33:25

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-11T15:33:19', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3b596827-3989-4719-a236-9b8e53eb0f35'	System	11 Aug 2020 20:33:25
User entered 'No (N)'	System	11 Aug 2020 20:33:25

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-11T15:33:21', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3b596827-3989-4719-a236-9b8e53eb0f35'	System	11 Aug 2020 20:33:25
User entered 'None (1)'	System	11 Aug 2020 20:33:25

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-11T15:33:23', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3b596827-3989-4719-a236-9b8e53eb0f35' User entered '11 Aug 2020 15:33'	System	11 Aug 2020 20:33:25
	System	11 Aug 2020 20:33:25

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T13:50:40', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'ad32049e-8795-4c05-80ad-9a8968c9149f' User entered 'None (0)'	System	05 Aug 2020 18:51:05
	System	05 Aug 2020 18:51:05

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T13:50:42', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'ad32049e-8795-4c05-80ad-9a8968c9149f' User entered 'None (0)'	System	05 Aug 2020 18:51:05
	System	05 Aug 2020 18:51:05

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T13:50:45', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'ad32049e-8795-4c05-80ad-9a8968c9149f' User entered 'None (0)'	System	05 Aug 2020 18:51:05
	System	05 Aug 2020 18:51:05

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T13:50:47', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'ad32049e-8795-4c05-80ad-9a8968c9149f' User entered 'None (0)'	System	05 Aug 2020 18:51:05
	System	05 Aug 2020 18:51:05

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T13:50:50', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'ad32049e-8795-4c05-80ad-9a8968c9149f' User entered 'None (0)'	System	05 Aug 2020 18:51:05
	System	05 Aug 2020 18:51:05

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T13:50:52', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'ad32049e-8795-4c05-80ad-9a8968c9149f' User entered 'None (0)'	System	05 Aug 2020 18:51:05
	System	05 Aug 2020 18:51:05

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T13:51:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'ad32049e-8795-4c05-80ad-9a8968c9149f' User entered 'No (N)'	System	05 Aug 2020 18:51:05
	System	05 Aug 2020 18:51:05

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T13:51:03', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'ad32049e-8795-4c05-80ad-9a8968c9149f' User entered '05 Aug 2020 13:51'	System	05 Aug 2020 18:51:05
	System	05 Aug 2020 18:51:05

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '05 Aug 2020 13:36'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '05 Aug 2020 16:06'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T18:23:04', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '36735f69-bfad-4504-9f9f-a5d9fcb2fc8e' User entered 'No interference with activity (1)'	System	05 Aug 2020 23:23:28
	System	05 Aug 2020 23:23:28

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T18:23:07', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '36735f69-bfad-4504-9f9f-a5d9fcb2fc8e' User entered 'None (0)'	System	05 Aug 2020 23:23:28
	System	05 Aug 2020 23:23:28

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T18:23:09', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '36735f69-bfad-4504-9f9f-a5d9fcb2fc8e' User entered 'None (0)'	System	05 Aug 2020 23:23:28
	System	05 Aug 2020 23:23:28

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T18:23:12', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '36735f69-bfad-4504-9f9f-a5d9fcb2fc8e' User entered 'None (0)'	System	05 Aug 2020 23:23:28
	System	05 Aug 2020 23:23:28

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T18:23:14', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '36735f69-bfad-4504-9f9f-a5d9fcb2fc8e' User entered 'None (0)'	System	05 Aug 2020 23:23:28
	System	05 Aug 2020 23:23:28

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T18:23:16', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '36735f69-bfad-4504-9f9f-a5d9fcb2fc8e' User entered 'None (0)'	System	05 Aug 2020 23:23:28
	System	05 Aug 2020 23:23:28

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T18:23:24', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '36735f69-bfad-4504-9f9f-a5d9fcb2fc8e' User entered 'No (N)'	System	05 Aug 2020 23:23:28
	System	05 Aug 2020 23:23:28

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-05T18:23:26', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '36735f69-bfad-4504-9f9f-a5d9fcb2fc8e'	System	05 Aug 2020 23:23:28
User entered '05 Aug 2020 18:23'	System	05 Aug 2020 23:23:28

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '05 Aug 2020 17:01'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 2'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-06T13:22:32', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '533c9e8d-2686-4ffb-bca1-7d7b7190e613' User entered 'None (0)'	System	06 Aug 2020 18:23:00
	System	06 Aug 2020 18:23:00

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-06T13:22:35', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '533c9e8d-2686-4ffb-bca1-7d7b7190e613' User entered 'None (0)'	System	06 Aug 2020 18:23:00
	System	06 Aug 2020 18:23:00

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-06T13:22:38', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '533c9e8d-2686-4ffb-bca1-7d7b7190e613' User entered 'None (0)'	System	06 Aug 2020 18:23:00
	System	06 Aug 2020 18:23:00

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-06T13:22:40', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '533c9e8d-2686-4ffb-bca1-7d7b7190e613' User entered 'None (0)'	System	06 Aug 2020 18:23:00
	System	06 Aug 2020 18:23:00

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-06T13:22:43', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '533c9e8d-2686-4ffb-bca1-7d7b7190e613' User entered 'None (0)'	System	06 Aug 2020 18:23:00
	System	06 Aug 2020 18:23:00

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-06T13:22:45', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '533c9e8d-2686-4ffb-bca1-7d7b7190e613' User entered 'None (0)'	System	06 Aug 2020 18:23:00
	System	06 Aug 2020 18:23:00

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-06T13:22:56', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '533c9e8d-2686-4ffb-bca1-7d7b7190e613' User entered 'No (N)'	System	06 Aug 2020 18:23:00
	System	06 Aug 2020 18:23:00

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-06T13:22:59', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '533c9e8d-2686-4ffb-bca1-7d7b7190e613' User entered '06 Aug 2020 13:22'	System	06 Aug 2020 18:23:00
	System	06 Aug 2020 18:23:00

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 3'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-07T14:18:51', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '57481659-83d2-4efa-a4da-077d8c822c8c' User entered 'None (0)'	System	07 Aug 2020 19:19:08
	System	07 Aug 2020 19:19:08

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-07T14:18:53', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '57481659-83d2-4efa-a4da-077d8c822c8c' User entered 'None (0)'	System	07 Aug 2020 19:19:08
	System	07 Aug 2020 19:19:08

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-07T14:18:55', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '57481659-83d2-4efa-a4da-077d8c822c8c' User entered 'None (0)'	System	07 Aug 2020 19:19:08
	System	07 Aug 2020 19:19:08

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-07T14:18:57', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '57481659-83d2-4efa-a4da-077d8c822c8c' User entered 'None (0)'	System	07 Aug 2020 19:19:08
	System	07 Aug 2020 19:19:08

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-07T14:18:58', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '57481659-83d2-4efa-a4da-077d8c822c8c' User entered 'None (0)'	System	07 Aug 2020 19:19:08
	System	07 Aug 2020 19:19:08

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-07T14:19:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '57481659-83d2-4efa-a4da-077d8c822c8c' User entered 'None (0)'	System	07 Aug 2020 19:19:08
	System	07 Aug 2020 19:19:08

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-07T14:19:04', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '57481659-83d2-4efa-a4da-077d8c822c8c' User entered 'No (N)'	System	07 Aug 2020 19:19:08
	System	07 Aug 2020 19:19:08

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-07T14:19:06', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '57481659-83d2-4efa-a4da-077d8c822c8c' User entered '07 Aug 2020 14:19'	System	07 Aug 2020 19:19:08
	System	07 Aug 2020 19:19:08

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 4'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-08T14:01:48', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '2a68558f-e9f4-443c-bce1-a3a95d29794c' User entered 'None (0)'	System	08 Aug 2020 19:02:08
	System	08 Aug 2020 19:02:08

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-08T14:01:52', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '2a68558f-e9f4-443c-bce1-a3a95d29794c' User entered 'None (0)'	System	08 Aug 2020 19:02:08
	System	08 Aug 2020 19:02:08

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-08T14:01:55', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '2a68558f-e9f4-443c-bce1-a3a95d29794c' User entered 'None (0)'	System	08 Aug 2020 19:02:08
	System	08 Aug 2020 19:02:08

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-08T14:01:57', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '2a68558f-e9f4-443c-bce1-a3a95d29794c' User entered 'None (0)'	System	08 Aug 2020 19:02:08
	System	08 Aug 2020 19:02:08

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-08T14:01:59', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '2a68558f-e9f4-443c-bce1-a3a95d29794c' User entered 'None (0)'	System	08 Aug 2020 19:02:08
	System	08 Aug 2020 19:02:08

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-08T14:02:01', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '2a68558f-e9f4-443c-bce1-a3a95d29794c' User entered 'None (0)'	System	08 Aug 2020 19:02:08
	System	08 Aug 2020 19:02:08

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-08T14:02:04', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '2a68558f-e9f4-443c-bce1-a3a95d29794c' User entered 'No (N)'	System	08 Aug 2020 19:02:08
	System	08 Aug 2020 19:02:08

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-08T14:02:06', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '2a68558f-e9f4-443c-bce1-a3a95d29794c' User entered '08 Aug 2020 14:02'	System	08 Aug 2020 19:02:08
	System	08 Aug 2020 19:02:08

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 5'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-09T14:15:28', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '134ad07f-4235-429b-a4cc-0de0d9d80adb' User entered 'None (0)'	System	09 Aug 2020 19:15:49
	System	09 Aug 2020 19:15:49

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-09T14:15:30', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '134ad07f-4235-429b-a4cc-0de0d9d80adb' User entered 'None (0)'	System	09 Aug 2020 19:15:49
	System	09 Aug 2020 19:15:49

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-09T14:15:32', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '134ad07f-4235-429b-a4cc-0de0d9d80adb' User entered 'None (0)'	System	09 Aug 2020 19:15:49
	System	09 Aug 2020 19:15:49

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-09T14:15:33', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '134ad07f-4235-429b-a4cc-0de0d9d80adb' User entered 'None (0)'	System	09 Aug 2020 19:15:49
	System	09 Aug 2020 19:15:49

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-09T14:15:35', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '134ad07f-4235-429b-a4cc-0de0d9d80adb' User entered 'None (0)'	System	09 Aug 2020 19:15:49
	System	09 Aug 2020 19:15:49

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-09T14:15:37', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '134ad07f-4235-429b-a4cc-0de0d9d80adb' User entered 'None (0)'	System	09 Aug 2020 19:15:49
	System	09 Aug 2020 19:15:49

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-09T14:15:45', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '134ad07f-4235-429b-a4cc-0de0d9d80adb' User entered 'No (N)'	System	09 Aug 2020 19:15:49
	System	09 Aug 2020 19:15:49

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-09T14:15:47', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '134ad07f-4235-429b-a4cc-0de0d9d80adb' User entered '09 Aug 2020 14:15'	System	09 Aug 2020 19:15:49
	System	09 Aug 2020 19:15:49

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 6'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-10T13:47:31', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '162a92bb-c14a-4e48-9878-be98a215c176' User entered 'None (0)'	System	10 Aug 2020 18:47:55
	System	10 Aug 2020 18:47:55

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-10T13:47:33', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '162a92bb-c14a-4e48-9878-be98a215c176' User entered 'None (0)'	System	10 Aug 2020 18:47:55
	System	10 Aug 2020 18:47:55

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-10T13:47:35', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '162a92bb-c14a-4e48-9878-be98a215c176' User entered 'None (0)'	System	10 Aug 2020 18:47:55
	System	10 Aug 2020 18:47:55

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-10T13:47:37', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '162a92bb-c14a-4e48-9878-be98a215c176' User entered 'None (0)'	System	10 Aug 2020 18:47:55
	System	10 Aug 2020 18:47:55

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-10T13:47:39', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '162a92bb-c14a-4e48-9878-be98a215c176' User entered 'None (0)'	System	10 Aug 2020 18:47:55
	System	10 Aug 2020 18:47:55

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-10T13:47:40', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '162a92bb-c14a-4e48-9878-be98a215c176' User entered 'None (0)'	System	10 Aug 2020 18:47:55
	System	10 Aug 2020 18:47:55

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-10T13:47:46', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '162a92bb-c14a-4e48-9878-be98a215c176' User entered 'No (N)'	System	10 Aug 2020 18:47:55
	System	10 Aug 2020 18:47:55

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-10T13:47:54', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '162a92bb-c14a-4e48-9878-be98a215c176' User entered '10 Aug 2020 13:47'	System	10 Aug 2020 18:47:55
	System	10 Aug 2020 18:47:55

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 7'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-11T15:32:57', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '71843084-c363-49af-b6ca-86f0e4803dd0' User entered 'None (0)'	System	11 Aug 2020 20:33:11
	System	11 Aug 2020 20:33:11

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-11T15:32:59', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '71843084-c363-49af-b6ca-86f0e4803dd0' User entered 'None (0)'	System	11 Aug 2020 20:33:11
	System	11 Aug 2020 20:33:11

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-11T15:33:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '71843084-c363-49af-b6ca-86f0e4803dd0' User entered 'None (0)'	System	11 Aug 2020 20:33:11
	System	11 Aug 2020 20:33:11

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-11T15:33:02', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '71843084-c363-49af-b6ca-86f0e4803dd0' User entered 'None (0)'	System	11 Aug 2020 20:33:11
	System	11 Aug 2020 20:33:11

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-11T15:33:04', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '71843084-c363-49af-b6ca-86f0e4803dd0' User entered 'None (0)'	System	11 Aug 2020 20:33:11
	System	11 Aug 2020 20:33:11

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-11T15:33:05', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '71843084-c363-49af-b6ca-86f0e4803dd0' User entered 'None (0)'	System	11 Aug 2020 20:33:11
	System	11 Aug 2020 20:33:11

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-11T15:33:08', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '71843084-c363-49af-b6ca-86f0e4803dd0' User entered 'No (N)'	System	11 Aug 2020 20:33:11
	System	11 Aug 2020 20:33:11

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-08-11T15:33:10', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '71843084-c363-49af-b6ca-86f0e4803dd0' User entered '11 Aug 2020 15:33'	System	11 Aug 2020 20:33:11
	System	11 Aug 2020 20:33:11

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 18:40:59

US3212049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	28 Aug 2020 22:41:32
User entered 'Yes (Y)'	Heather Leary (b) (4)	18 Aug 2020 20:31:07

US3212049

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	28 Aug 2020 22:41:32
User entered '12 Aug 2020'	Heather Leary (b) (4)	18 Aug 2020 20:31:07

US3212049

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	28 Aug 2020 22:41:32
User entered 'Contact Made (CONTACT MADE)'	Heather Leary (b) (4)	18 Aug 2020 20:31:07

US3212049

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	28 Aug 2020 22:41:32
User entered empty.	Heather Leary (b) (4)	18 Aug 2020 20:31:07

US3212049

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:33:46
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
User entered 'Yes (Y)'	Heather Leary (b) (4)	18 Aug 2020 20:31:10

US3212049

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'I'	System	18 Aug 2020 20:31:10

US3212049

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:37:28
User entered 'Yes (Y)'	Heather Leary (b) (4)	20 Aug 2020 22:31:54

US3212049

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:37:28
User entered '19 Aug 2020'	Heather Leary (b) (4)	20 Aug 2020 22:31:54

US3212049

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:37:28
User entered 'Contact Made (CONTACT MADE)'	Heather Leary (b) (4)	20 Aug 2020 22:31:54

US3212049

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:37:28
User entered empty.	Heather Leary (b) (4)	20 Aug 2020 22:31:54

US3212049

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:37:43
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	27 Aug 2020 14:03:37

US3212049

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'I'	System	27 Aug 2020 14:03:37

US3212049

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:39:30
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	27 Aug 2020 14:03:51

US3212049

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:39:30
User entered '26 Aug 2020'	Laura Ngansop Djampou (b) (4)	27 Aug 2020 14:03:51

US3212049

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:39:30
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	27 Aug 2020 14:03:51

US3212049

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:39:30
User entered empty.	Laura Ngansop Djampou (b) (4)	27 Aug 2020 14:03:51

US3212049

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:39:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	27 Aug 2020 14:03:59

US3212049

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'I'	System	27 Aug 2020 14:03:59

US3212049

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:45:00
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	09 Sep 2020 17:38:41

US3212049

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:39:37
User entered '09 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:39:37
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:45:00
User entered '9 Sep 2020'	Afifah Ayub (b) (4)	09 Sep 2020 17:38:41

US3212049

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:30

[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 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:45:00
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4)	09 Sep 2020 17:38:41

US3212049

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'VISIT2'	System	09 Sep 2020 17:38:41

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User accepted default value 'Pre-Dose (PREDOSE)'	Laura Ngansop Djampou	09 Sep 2020 18:26:06
	(b) (4)	

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:46:15
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 18:26:06

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:34:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:39:46
User entered '09 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:39:46
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:46:15
User entered '9 Sep 2020'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 18:26:06

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:46:15
User entered '11:42'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 18:26:06

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered '09 Sep 2020 11:42'	System	02 Dec 2020 20:39:46
User entered '9 Sep 2020 11:42'	System	09 Sep 2020 18:26:06

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:46:15
User entered '97.3' F	Laura Ngansop Djampou (b) (4)	09 Sep 2020 18:26:06

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:46:15
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 18:26:06

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:46:15
User entered empty.	Laura Ngansop Djampou (b) (4)	09 Sep 2020 18:26:06

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:46:15
User entered '66'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 18:26:06

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'bpm'	System	09 Sep 2020 18:26:06

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:46:15
User entered '16'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 18:26:06

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'breaths/min'	System	09 Sep 2020 18:26:06

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:46:15
User entered '145'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 18:26:06

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'mmHg'	System	09 Sep 2020 18:26:06

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:46:15
User entered '84'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 18:26:06

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:46:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'mmHg'	System	09 Sep 2020 18:26:06

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User accepted default value 'Post-Dose (POSTDOSE)'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 18:26:59

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:46:15
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 18:26:59

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:34:26
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:39:46
User entered '09 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:39:46
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:46:15
User entered '9 Sep 2020'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 18:26:59

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:46:15
User entered '13:13'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 18:26:59

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered '09 Sep 2020 13:13'	System	02 Dec 2020 20:39:46
User entered '9 Sep 2020 13:13'	System	09 Sep 2020 18:26:59

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:46:15
User entered '97.8' F	Laura Ngansop Djampou (b) (4)	09 Sep 2020 18:26:59

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:46:15
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 18:26:59

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:46:15
User entered empty.	Laura Ngansop Djampou (b) (4)	09 Sep 2020 18:26:59

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:46:15
User entered '62'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 18:26:59

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'bpm'	System	09 Sep 2020 18:26:59

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:46:15
User entered '15'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 18:26:59

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'breaths/min'	System	09 Sep 2020 18:26:59

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:46:15
User entered '143'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 18:26:59

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'mmHg'	System	09 Sep 2020 18:26:59

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:46:15
User entered '83'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 18:26:59

US3212049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:46:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'mmHg'	System	09 Sep 2020 18:26:59

US3212049

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:46:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	09 Sep 2020 17:38:54

US3212049

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:34:30
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:39:52
User entered '09 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:39:52
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:46:33
User entered '9 Sep 2020'	Afifah Ayub (b) (4)	09 Sep 2020 17:38:54

US3212049

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:47:05
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	09 Sep 2020 17:39:22

US3212049

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:47:05
User entered empty.	Afifah Ayub (b) (4)	09 Sep 2020 17:39:22

US3212049

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:30

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 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:47:05
User entered empty.	Afifah Ayub (b) (4)	09 Sep 2020 17:39:22

US3212049

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 17:39:22

US3212049

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:34:34
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:40:07
User entered '09 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:40:07
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:47:05
User entered '9 Sep 2020'	Afifah Ayub (b) (4)	09 Sep 2020 17:39:22

US3212049

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:47:05
User entered '12:32'	Afifah Ayub (b) (4)	09 Sep 2020 17:39:22

US3212049

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered '09 Sep 2020 12:32'	System	02 Dec 2020 20:40:07
User entered '9 Sep 2020 12:32'	System	09 Sep 2020 17:39:22

US3212049

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:47:05
User entered 'Left Arm (LEFT ARM)'	Afifah Ayub (b) (4)	09 Sep 2020 17:39:22

US3212049

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:47:05
User entered 'ONCE'	System	09 Sep 2020 17:39:22

US3212049

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 17:39:22

US3212049

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:47:14
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	09 Sep 2020 17:39:33

US3212049

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:34:05
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:39:59
User entered '09 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:39:59
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:47:14
User entered '9 Sep 2020'	Afifah Ayub (b) (4)	09 Sep 2020 17:39:33

US3212049

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:47:14
User entered '12:19'	Afifah Ayub (b) (4)	09 Sep 2020 17:39:33

US3212049

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered '09 Sep 2020 12:19'	System	02 Dec 2020 20:39:59
User entered '9 Sep 2020 12:19'	System	09 Sep 2020 17:39:33

US3212049

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:46:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:34:42
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:40:17
User entered '09 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:40:17
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:47:25
User entered '9 Sep 2020'	Afifah Ayub (b) (4)	09 Sep 2020 17:39:43

US3212049

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:46:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Afifah Ayub (b) (4) (b) (4)	09 Sep 2020 17:39:43

US3212049

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:46:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:47:25
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	09 Sep 2020 17:39:43

US3212049

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:47:25
User entered '12:14'	Afifah Ayub (b) (4)	09 Sep 2020 17:39:43

US3212049

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered '09 Sep 2020 12:14'	System	02 Dec 2020 20:40:17
User entered '9 Sep 2020 12:14'	System	09 Sep 2020 17:39:43

US3212049

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:46:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Afifah Ayub (b) (4)	09 Sep 2020 17:39:43

US3212049

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:46:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:47:25
User entered 'No (N)'	Afifah Ayub (b) (4)	09 Sep 2020 17:39:43

US3212049

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:46:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:47:25
User entered empty.	Afifah Ayub (b) (4)	09 Sep 2020 17:39:43

US3212049

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered empty.	System	09 Sep 2020 17:39:43

US3212049

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:47:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	09 Sep 2020 17:40:36

US3212049

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'I'	System	09 Sep 2020 17:40:36

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	09 Sep 2020 17:39:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T13:11:29', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '232dad7e-4798-47d8-9ea8-cddf247c0695' User entered 'Yes (Y)'	System	09 Sep 2020 18:12:16
	System	09 Sep 2020 18:12:16

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T13:12:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '232dad7e-4798-47d8-9ea8-cddf247c0695' User entered '97.8'	System	09 Sep 2020 18:12:16
	System	09 Sep 2020 18:12:16

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T13:12:05', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '232dad7e-4798-47d8-9ea8-cddf247c0695'	System	09 Sep 2020 18:12:16
User entered 'No (N)'	System	09 Sep 2020 18:12:16

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T13:12:12', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '232dad7e-4798-47d8-9ea8-cddf247c0695' User entered '09 Sep 2020 13:12'	System	09 Sep 2020 18:12:16
	System	09 Sep 2020 18:12:16

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '09 Sep 2020 12:52'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '09 Sep 2020 15:22'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	09 Sep 2020 17:39:22
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T17:19:59', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '96707199-f23a-43db-903c-d77cf34b5bc2' User entered 'Yes (Y)'	System	09 Sep 2020 22:20:16
	System	09 Sep 2020 22:20:16

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T17:20:05', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '96707199-f23a-43db-903c-d77cf34b5bc2' User entered '98.6'	System	09 Sep 2020 22:20:16
	System	09 Sep 2020 22:20:16

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T17:20:10', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '96707199-f23a-43db-903c-d77cf34b5bc2' User entered 'No (N)'	System	09 Sep 2020 22:20:16
	System	09 Sep 2020 22:20:16

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T17:20:14', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '96707199-f23a-43db-903c-d77cf34b5bc2' User entered '09 Sep 2020 17:20'	System	09 Sep 2020 22:20:16
	System	09 Sep 2020 22:20:16

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '09 Sep 2020 16:17'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	09 Sep 2020 17:39:22
User entered 'Day 2'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:30

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-10T12:17:21', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '211c2704-1ea7-4d32-a7ec-4a926159f8af' User entered 'Yes (Y)'	System	10 Sep 2020 17:17:37
	System	10 Sep 2020 17:17:37

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-10T12:17:26', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '211c2704-1ea7-4d32-a7ec-4a926159f8af' User entered '98.8'	System	10 Sep 2020 17:17:37
	System	10 Sep 2020 17:17:37

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-10T12:17:31', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '211c2704-1ea7-4d32-a7ec-4a926159f8af' User entered 'No (N)'	System	10 Sep 2020 17:17:37
	System	10 Sep 2020 17:17:37

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-10T12:17:34', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '211c2704-1ea7-4d32-a7ec-4a926159f8af' User entered '10 Sep 2020 12:17'	System	10 Sep 2020 17:17:37
	System	10 Sep 2020 17:17:37

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	09 Sep 2020 17:39:22
User entered 'Day 3'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:30

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-11T18:54:30', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'd4e3fcd8-c1aa-4d8e-99ce-2f11af76153f' User entered 'Yes (Y)'	System	11 Sep 2020 23:55:13
	System	11 Sep 2020 23:55:13

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:30

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-11T18:55:02', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'd4e3fcd8-c1aa-4d8e-99ce-2f11af76153f' User entered '98.9'	System	11 Sep 2020 23:55:13
	System	11 Sep 2020 23:55:13

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-11T18:55:06', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'd4e3fcd8-c1aa-4d8e-99ce-2f11af76153f' User entered 'No (N)'	System	11 Sep 2020 23:55:13
	System	11 Sep 2020 23:55:13

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-11T18:55:09', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'd4e3fcd8-c1aa-4d8e-99ce-2f11af76153f' User entered '11 Sep 2020 18:55'	System	11 Sep 2020 23:55:13
	System	11 Sep 2020 23:55:13

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	09 Sep 2020 17:39:22
User entered 'Day 4'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:30

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-12T15:22:10', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '2529bc50-4185-41d6-8694-ee8d7a18e4ff' User entered 'Yes (Y)'	System	12 Sep 2020 20:23:26
	System	12 Sep 2020 20:23:26

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-12T15:23:19', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '2529bc50-4185-41d6-8694-ee8d7a18e4ff' User entered '97.9'	System	12 Sep 2020 20:23:26
	System	12 Sep 2020 20:23:26

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-12T15:23:22', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '2529bc50-4185-41d6-8694-ee8d7a18e4ff' User entered 'No (N)'	System	12 Sep 2020 20:23:26
	System	12 Sep 2020 20:23:26

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-12T15:23:24', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '2529bc50-4185-41d6-8694-ee8d7a18e4ff' User entered '12 Sep 2020 15:23'	System	12 Sep 2020 20:23:26
	System	12 Sep 2020 20:23:26

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	09 Sep 2020 17:39:22
User entered 'Day 5'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:30

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-13T12:20:53', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '542380d2-0cd5-4c91-90ab-7b5896b15164' User entered 'Yes (Y)'	System	13 Sep 2020 17:21:15
	System	13 Sep 2020 17:21:15

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-13T12:20:58', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '542380d2-0cd5-4c91-90ab-7b5896b15164' User entered '97.7'	System	13 Sep 2020 17:21:15
	System	13 Sep 2020 17:21:15

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-13T12:21:02', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '542380d2-0cd5-4c91-90ab-7b5896b15164' User entered 'No (N)'	System	13 Sep 2020 17:21:15
	System	13 Sep 2020 17:21:15

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-13T12:21:05', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '542380d2-0cd5-4c91-90ab-7b5896b15164' User entered '13 Sep 2020 12:21'	System	13 Sep 2020 17:21:15
	System	13 Sep 2020 17:21:15

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	09 Sep 2020 17:39:22
User entered 'Day 6'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:30

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-14T12:00:18', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'e525c856-250e-4f50-aeae-7144959c51a8' User entered 'No (N)'	System	14 Sep 2020 17:00:39
	System	14 Sep 2020 17:00:39

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-14T12:00:22', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'e525c856-250e-4f50-aeae-7144959c51a8' User entered 'No (N)'	System	14 Sep 2020 17:00:39
	System	14 Sep 2020 17:00:39

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-14T12:00:27', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'e525c856-250e-4f50-aeae-7144959c51a8' User entered '14 Sep 2020 12:00'	System	14 Sep 2020 17:00:39
	System	14 Sep 2020 17:00:39

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	09 Sep 2020 17:39:22
User entered 'Day 7'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:30

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-15T16:06:53', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '47a158c3-f613-4f5c-8a6f-421e74111d7c' User entered 'Yes (Y)'	System	15 Sep 2020 21:07:11
	System	15 Sep 2020 21:07:11

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-15T16:07:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '47a158c3-f613-4f5c-8a6f-421e74111d7c' User entered '98.9'	System	15 Sep 2020 21:07:11
	System	15 Sep 2020 21:07:11

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-15T16:07:03', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '47a158c3-f613-4f5c-8a6f-421e74111d7c' User entered 'No (N)'	System	15 Sep 2020 21:07:11
	System	15 Sep 2020 21:07:11

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-15T16:07:06', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '47a158c3-f613-4f5c-8a6f-421e74111d7c' User entered '15 Sep 2020 16:07'	System	15 Sep 2020 21:07:11
	System	15 Sep 2020 21:07:11

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	09 Sep 2020 17:39:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T13:12:24', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '776573dc-dd62-4a5a-9868-04e1ef0b5e46' User entered 'None (1)'	System	09 Sep 2020 18:12:58
	System	09 Sep 2020 18:12:58

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T13:12:43', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '776573dc-dd62-4a5a-9868-04e1ef0b5e46' User entered 'No (N)'	System	09 Sep 2020 18:12:58
	System	09 Sep 2020 18:12:58

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T13:12:46', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '776573dc-dd62-4a5a-9868-04e1ef0b5e46' User entered 'No (N)'	System	09 Sep 2020 18:12:58
	System	09 Sep 2020 18:12:58

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T13:12:51', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '776573dc-dd62-4a5a-9868-04e1ef0b5e46' User entered 'None (1)'	System	09 Sep 2020 18:12:58
	System	09 Sep 2020 18:12:58

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T13:12:54', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '776573dc-dd62-4a5a-9868-04e1ef0b5e46' User entered '09 Sep 2020 13:12'	System	09 Sep 2020 18:12:58
	System	09 Sep 2020 18:12:58

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '09 Sep 2020 12:52'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '09 Sep 2020 15:22'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	09 Sep 2020 17:39:22
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T17:20:34', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'd26f8e76-7aaf-4c01-829c-576022942797'	System	09 Sep 2020 22:20:58
User entered 'None (1)'	System	09 Sep 2020 22:20:58

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T17:20:36', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'd26f8e76-7aaf-4c01-829c-576022942797' User entered 'No (N)'	System	09 Sep 2020 22:20:58
	System	09 Sep 2020 22:20:58

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T17:20:43', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'd26f8e76-7aaf-4c01-829c-576022942797' User entered 'No (N)'	System	09 Sep 2020 22:20:58
	System	09 Sep 2020 22:20:58

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T17:20:48', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'd26f8e76-7aaf-4c01-829c-576022942797' User entered 'None (1)'	System	09 Sep 2020 22:20:58
	System	09 Sep 2020 22:20:58

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T17:20:53', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'd26f8e76-7aaf-4c01-829c-576022942797' User entered '09 Sep 2020 17:20'	System	09 Sep 2020 22:20:58
	System	09 Sep 2020 22:20:58

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '09 Sep 2020 16:17'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	09 Sep 2020 17:39:22
User entered 'Day 2'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-10T12:17:42', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '18e1ea5a-fb29-4b84-b527-2eb3d0dc90fe'	System	10 Sep 2020 17:18:40
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 17:18:40

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-10T12:18:18', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '18e1ea5a-fb29-4b84-b527-2eb3d0dc90fe' User entered 'No (N)'	System	10 Sep 2020 17:18:40
	System	10 Sep 2020 17:18:40

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-10T12:18:31', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '18e1ea5a-fb29-4b84-b527-2eb3d0dc90fe' User entered 'No (N)'	System	10 Sep 2020 17:18:40
	System	10 Sep 2020 17:18:40

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-10T12:18:36', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '18e1ea5a-fb29-4b84-b527-2eb3d0dc90fe' User entered 'None (1)'	System	10 Sep 2020 17:18:40
	System	10 Sep 2020 17:18:40

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-10T12:18:39', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '18e1ea5a-fb29-4b84-b527-2eb3d0dc90fe' User entered '10 Sep 2020 12:18'	System	10 Sep 2020 17:18:40
	System	10 Sep 2020 17:18:40

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	09 Sep 2020 17:39:22
User entered 'Day 3'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-11T18:53:51', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '1c0a20b1-6761-44c2-8e11-d254f3fb2322'	System	11 Sep 2020 23:54:12
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 23:54:12

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-11T18:53:54', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '1c0a20b1-6761-44c2-8e11-d254f3fb2322'	System	11 Sep 2020 23:54:12
User entered 'No (N)'	System	11 Sep 2020 23:54:12

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-11T18:53:56', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '1c0a20b1-6761-44c2-8e11-d254f3fb2322'	System	11 Sep 2020 23:54:12
User entered 'No (N)'	System	11 Sep 2020 23:54:12

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-11T18:53:59', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '1c0a20b1-6761-44c2-8e11-d254f3fb2322'	System	11 Sep 2020 23:54:12
User entered 'None (1)'	System	11 Sep 2020 23:54:12

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-11T18:54:08', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '1c0a20b1-6761-44c2-8e11-d254f3fb2322'	System	11 Sep 2020 23:54:12
User entered '11 Sep 2020 18:54'	System	11 Sep 2020 23:54:12

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	09 Sep 2020 17:39:22
User entered 'Day 4'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-12T15:23:28', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '31b53813-f8df-4adb-ab7a-62e298f0b539'	System	12 Sep 2020 20:23:38
User entered 'None (1)'	System	12 Sep 2020 20:23:38

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-12T15:23:30', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '31b53813-f8df-4adb-ab7a-62e298f0b539' User entered 'No (N)'	System	12 Sep 2020 20:23:38
	System	12 Sep 2020 20:23:38

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-12T15:23:32', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '31b53813-f8df-4adb-ab7a-62e298f0b539' User entered 'No (N)'	System	12 Sep 2020 20:23:38
	System	12 Sep 2020 20:23:38

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-12T15:23:34', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '31b53813-f8df-4adb-ab7a-62e298f0b539' User entered 'None (1)'	System	12 Sep 2020 20:23:38
	System	12 Sep 2020 20:23:38

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-12T15:23:36', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '31b53813-f8df-4adb-ab7a-62e298f0b539' User entered '12 Sep 2020 15:23'	System	12 Sep 2020 20:23:38
	System	12 Sep 2020 20:23:38

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	09 Sep 2020 17:39:22
User entered 'Day 5'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-13T12:21:10', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'daa9a2c3-7b80-4d8d-a6fc-56f2547bf575'	System	13 Sep 2020 17:21:23
User entered 'None (1)'	System	13 Sep 2020 17:21:23

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-13T12:21:12', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'daa9a2c3-7b80-4d8d-a6fc-56f2547bf575'	System	13 Sep 2020 17:21:23
User entered 'No (N)'	System	13 Sep 2020 17:21:23

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-13T12:21:14', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'daa9a2c3-7b80-4d8d-a6fc-56f2547bf575'	System	13 Sep 2020 17:21:23
User entered 'No (N)'	System	13 Sep 2020 17:21:23

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-13T12:21:16', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'daa9a2c3-7b80-4d8d-a6fc-56f2547bf575'	System	13 Sep 2020 17:21:23
User entered 'None (1)'	System	13 Sep 2020 17:21:23

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-13T12:21:18', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'daa9a2c3-7b80-4d8d-a6fc-56f2547bf575'	System	13 Sep 2020 17:21:23
User entered '13 Sep 2020 12:21'	System	13 Sep 2020 17:21:23

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	09 Sep 2020 17:39:22
User entered 'Day 6'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-14T12:00:31', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '702c3cfc-8171-4d1a-9d8f-69f36ad30722'	System	14 Sep 2020 17:01:05
User entered 'None (1)'	System	14 Sep 2020 17:01:05

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-14T12:00:34', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '702c3cfc-8171-4d1a-9d8f-69f36ad30722'	System	14 Sep 2020 17:01:05
User entered 'No (N)'	System	14 Sep 2020 17:01:05

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-14T12:00:35', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '702c3cfc-8171-4d1a-9d8f-69f36ad30722'	System	14 Sep 2020 17:01:05
User entered 'No (N)'	System	14 Sep 2020 17:01:05

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-14T12:00:37', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '702c3cfc-8171-4d1a-9d8f-69f36ad30722'	System	14 Sep 2020 17:01:05
User entered 'None (1)'	System	14 Sep 2020 17:01:05

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-14T12:00:40', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '702c3cfc-8171-4d1a-9d8f-69f36ad30722'	System	14 Sep 2020 17:01:05
User entered '14 Sep 2020 12:00'	System	14 Sep 2020 17:01:05

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	09 Sep 2020 17:39:22
User entered 'Day 7'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-15T16:07:09', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '8233b9f6-863d-462b-84a3-362d46c9d31a' User entered 'None (1)'	System	15 Sep 2020 21:07:22
	System	15 Sep 2020 21:07:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-15T16:07:12', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '8233b9f6-863d-462b-84a3-362d46c9d31a' User entered 'No (N)'	System	15 Sep 2020 21:07:22
	System	15 Sep 2020 21:07:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-15T16:07:13', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '8233b9f6-863d-462b-84a3-362d46c9d31a' User entered 'No (N)'	System	15 Sep 2020 21:07:22
	System	15 Sep 2020 21:07:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-15T16:07:15', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '8233b9f6-863d-462b-84a3-362d46c9d31a' User entered 'None (1)'	System	15 Sep 2020 21:07:22
	System	15 Sep 2020 21:07:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-15T16:07:17', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '8233b9f6-863d-462b-84a3-362d46c9d31a' User entered '15 Sep 2020 16:07'	System	15 Sep 2020 21:07:22
	System	15 Sep 2020 21:07:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	09 Sep 2020 17:39:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T13:12:59', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '6898ffcf-46af-4a1d-9553-5e62865136a6' User entered 'None (0)'	System	09 Sep 2020 18:13:26
	System	09 Sep 2020 18:13:26

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T13:13:06', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '6898ffcf-46af-4a1d-9553-5e62865136a6' User entered 'None (0)'	System	09 Sep 2020 18:13:26
	System	09 Sep 2020 18:13:26

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T13:13:08', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '6898ffcf-46af-4a1d-9553-5e62865136a6' User entered 'None (0)'	System	09 Sep 2020 18:13:26
	System	09 Sep 2020 18:13:26

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T13:13:10', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '6898ffcf-46af-4a1d-9553-5e62865136a6' User entered 'None (0)'	System	09 Sep 2020 18:13:26
	System	09 Sep 2020 18:13:26

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T13:13:12', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '6898ffcf-46af-4a1d-9553-5e62865136a6' User entered 'None (0)'	System	09 Sep 2020 18:13:26
	System	09 Sep 2020 18:13:26

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T13:13:14', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '6898ffcf-46af-4a1d-9553-5e62865136a6' User entered 'None (0)'	System	09 Sep 2020 18:13:26
	System	09 Sep 2020 18:13:26

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T13:13:21', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '6898ffcf-46af-4a1d-9553-5e62865136a6' User entered 'No (N)'	System	09 Sep 2020 18:13:26
	System	09 Sep 2020 18:13:26

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T13:13:23', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '6898ffcf-46af-4a1d-9553-5e62865136a6' User entered '09 Sep 2020 13:13'	System	09 Sep 2020 18:13:26
	System	09 Sep 2020 18:13:26

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '09 Sep 2020 12:52'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '09 Sep 2020 15:22'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	09 Sep 2020 17:39:22
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T17:21:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3d88d790-d81f-4aff-9a27-07771d67d1d9' User entered 'None (0)'	System	09 Sep 2020 22:21:19
	System	09 Sep 2020 22:21:19

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T17:21:03', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3d88d790-d81f-4aff-9a27-07771d67d1d9' User entered 'None (0)'	System	09 Sep 2020 22:21:19
	System	09 Sep 2020 22:21:19

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T17:21:04', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3d88d790-d81f-4aff-9a27-07771d67d1d9' User entered 'None (0)'	System	09 Sep 2020 22:21:19
	System	09 Sep 2020 22:21:19

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T17:21:06', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3d88d790-d81f-4aff-9a27-07771d67d1d9' User entered 'None (0)'	System	09 Sep 2020 22:21:19
	System	09 Sep 2020 22:21:19

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T17:21:08', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3d88d790-d81f-4aff-9a27-07771d67d1d9' User entered 'None (0)'	System	09 Sep 2020 22:21:19
	System	09 Sep 2020 22:21:19

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T17:21:09', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3d88d790-d81f-4aff-9a27-07771d67d1d9' User entered 'None (0)'	System	09 Sep 2020 22:21:19
	System	09 Sep 2020 22:21:19

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T17:21:14', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3d88d790-d81f-4aff-9a27-07771d67d1d9' User entered 'No (N)'	System	09 Sep 2020 22:21:19
	System	09 Sep 2020 22:21:19

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-09T17:21:17', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3d88d790-d81f-4aff-9a27-07771d67d1d9' User entered '09 Sep 2020 17:21'	System	09 Sep 2020 22:21:19
	System	09 Sep 2020 22:21:19

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '09 Sep 2020 16:17'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	09 Sep 2020 17:39:22
User entered 'Day 2'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-10T12:18:43', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'd146decc-901c-48af-9743-b42d3490cff6'	System	10 Sep 2020 17:19:03
User entered 'No interference with activity (1)'	System	10 Sep 2020 17:19:03

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-10T12:18:47', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'd146decc-901c-48af-9743-b42d3490cff6' User entered 'None (0)'	System	10 Sep 2020 17:19:03
	System	10 Sep 2020 17:19:03

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-10T12:18:50', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'd146decc-901c-48af-9743-b42d3490cff6' User entered 'None (0)'	System	10 Sep 2020 17:19:03
	System	10 Sep 2020 17:19:03

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-10T12:18:53', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'd146decc-901c-48af-9743-b42d3490cff6' User entered 'None (0)'	System	10 Sep 2020 17:19:03
	System	10 Sep 2020 17:19:03

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-10T12:18:55', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'd146decc-901c-48af-9743-b42d3490cff6' User entered 'None (0)'	System	10 Sep 2020 17:19:03
	System	10 Sep 2020 17:19:03

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-10T12:18:57', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'd146decc-901c-48af-9743-b42d3490cff6' User entered 'None (0)'	System	10 Sep 2020 17:19:03
	System	10 Sep 2020 17:19:03

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-10T12:18:59', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'd146decc-901c-48af-9743-b42d3490cff6' User entered 'No (N)'	System	10 Sep 2020 17:19:03
	System	10 Sep 2020 17:19:03

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-10T12:19:02', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'd146decc-901c-48af-9743-b42d3490cff6'	System	10 Sep 2020 17:19:03
User entered '10 Sep 2020 12:19'	System	10 Sep 2020 17:19:03

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	09 Sep 2020 17:39:22
User entered 'Day 3'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-11T18:53:20', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '1a5eabbb-cdc7-4bc9-bd29-95535e539b59' User entered 'None (0)'	System	11 Sep 2020 23:53:46
	System	11 Sep 2020 23:53:46

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-11T18:53:22', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '1a5eabbb-cdc7-4bc9-bd29-95535e539b59' User entered 'None (0)'	System	11 Sep 2020 23:53:46
	System	11 Sep 2020 23:53:46

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-11T18:53:24', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '1a5eabbb-cdc7-4bc9-bd29-95535e539b59' User entered 'None (0)'	System	11 Sep 2020 23:53:46
	System	11 Sep 2020 23:53:46

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-11T18:53:26', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '1a5eabbb-cdc7-4bc9-bd29-95535e539b59' User entered 'None (0)'	System	11 Sep 2020 23:53:46
	System	11 Sep 2020 23:53:46

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-11T18:53:32', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '1a5eabbb-cdc7-4bc9-bd29-95535e539b59' User entered 'None (0)'	System	11 Sep 2020 23:53:46
	System	11 Sep 2020 23:53:46

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-11T18:53:35', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '1a5eabbb-cdc7-4bc9-bd29-95535e539b59' User entered 'None (0)'	System	11 Sep 2020 23:53:46
	System	11 Sep 2020 23:53:46

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-11T18:53:42', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '1a5eabbb-cdc7-4bc9-bd29-95535e539b59' User entered 'No (N)'	System	11 Sep 2020 23:53:46
	System	11 Sep 2020 23:53:46

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-11T18:53:44', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '1a5eabbb-cdc7-4bc9-bd29-95535e539b59' User entered '11 Sep 2020 18:53'	System	11 Sep 2020 23:53:46
	System	11 Sep 2020 23:53:46

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	09 Sep 2020 17:39:22
User entered 'Day 4'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-12T15:23:40', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3788119d-b4a0-4e99-97e3-f9da55b8d3d3' User entered 'None (0)'	System	12 Sep 2020 20:23:55
	System	12 Sep 2020 20:23:55

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-12T15:23:42', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3788119d-b4a0-4e99-97e3-f9da55b8d3d3' User entered 'None (0)'	System	12 Sep 2020 20:23:55
	System	12 Sep 2020 20:23:55

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-12T15:23:44', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3788119d-b4a0-4e99-97e3-f9da55b8d3d3' User entered 'None (0)'	System	12 Sep 2020 20:23:55
	System	12 Sep 2020 20:23:55

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-12T15:23:45', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3788119d-b4a0-4e99-97e3-f9da55b8d3d3' User entered 'None (0)'	System	12 Sep 2020 20:23:55
	System	12 Sep 2020 20:23:55

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-12T15:23:47', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3788119d-b4a0-4e99-97e3-f9da55b8d3d3' User entered 'None (0)'	System	12 Sep 2020 20:23:55
	System	12 Sep 2020 20:23:55

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-12T15:23:48', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3788119d-b4a0-4e99-97e3-f9da55b8d3d3' User entered 'None (0)'	System	12 Sep 2020 20:23:55
	System	12 Sep 2020 20:23:55

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-12T15:23:51', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3788119d-b4a0-4e99-97e3-f9da55b8d3d3' User entered 'No (N)'	System	12 Sep 2020 20:23:55
	System	12 Sep 2020 20:23:55

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-12T15:23:53', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3788119d-b4a0-4e99-97e3-f9da55b8d3d3' User entered '12 Sep 2020 15:23'	System	12 Sep 2020 20:23:55
	System	12 Sep 2020 20:23:55

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	09 Sep 2020 17:39:22
User entered 'Day 5'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-13T12:21:25', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '06161628-ef86-4187-820b-df13ca263f44' User entered 'None (0)'	System	13 Sep 2020 17:22:00
	System	13 Sep 2020 17:22:00

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-13T12:21:26', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '06161628-ef86-4187-820b-df13ca263f44' User entered 'None (0)'	System	13 Sep 2020 17:22:00
	System	13 Sep 2020 17:22:00

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-13T12:21:28', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '06161628-ef86-4187-820b-df13ca263f44' User entered 'None (0)'	System	13 Sep 2020 17:22:00
	System	13 Sep 2020 17:22:00

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-13T12:21:29', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '06161628-ef86-4187-820b-df13ca263f44' User entered 'None (0)'	System	13 Sep 2020 17:22:00
	System	13 Sep 2020 17:22:00

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-13T12:21:31', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '06161628-ef86-4187-820b-df13ca263f44' User entered 'None (0)'	System	13 Sep 2020 17:22:00
	System	13 Sep 2020 17:22:00

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-13T12:21:32', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '06161628-ef86-4187-820b-df13ca263f44' User entered 'None (0)'	System	13 Sep 2020 17:22:00
	System	13 Sep 2020 17:22:00

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-13T12:21:35', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '06161628-ef86-4187-820b-df13ca263f44' User entered 'No (N)'	System	13 Sep 2020 17:22:00
	System	13 Sep 2020 17:22:00

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-13T12:21:37', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '06161628-ef86-4187-820b-df13ca263f44' User entered '13 Sep 2020 12:21'	System	13 Sep 2020 17:22:00
	System	13 Sep 2020 17:22:00

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	09 Sep 2020 17:39:22
User entered 'Day 6'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-14T12:00:44', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '7b3d8989-efd7-4e12-b6c0-7aeefb32a0f2' User entered 'None (0)'	System	14 Sep 2020 17:01:40
	System	14 Sep 2020 17:01:40

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-14T12:00:46', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '7b3d8989-efd7-4e12-b6c0-7aeefb32a0f2' User entered 'None (0)'	System	14 Sep 2020 17:01:40
	System	14 Sep 2020 17:01:40

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-14T12:00:48', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '7b3d8989-efd7-4e12-b6c0-7aeefb32a0f2' User entered 'None (0)'	System	14 Sep 2020 17:01:40
	System	14 Sep 2020 17:01:40

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-14T12:00:49', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '7b3d8989-efd7-4e12-b6c0-7aeefb32a0f2' User entered 'None (0)'	System	14 Sep 2020 17:01:40
	System	14 Sep 2020 17:01:40

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-14T12:00:51', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '7b3d8989-efd7-4e12-b6c0-7aeefb32a0f2' User entered 'None (0)'	System	14 Sep 2020 17:01:40
	System	14 Sep 2020 17:01:40

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-14T12:00:53', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '7b3d8989-efd7-4e12-b6c0-7aeefb32a0f2' User entered 'None (0)'	System	14 Sep 2020 17:01:40
	System	14 Sep 2020 17:01:40

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-14T12:00:55', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '7b3d8989-efd7-4e12-b6c0-7aeefb32a0f2' User entered 'No (N)'	System	14 Sep 2020 17:01:40
	System	14 Sep 2020 17:01:40

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-14T12:00:57', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '7b3d8989-efd7-4e12-b6c0-7aeefb32a0f2' User entered '14 Sep 2020 12:00'	System	14 Sep 2020 17:01:40
	System	14 Sep 2020 17:01:40

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	09 Sep 2020 17:39:22
User entered 'Day 7'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-15T16:07:20', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '85da7d2c-f1b8-4248-ba90-ac060b31070e' User entered 'None (0)'	System	15 Sep 2020 21:07:38
	System	15 Sep 2020 21:07:38

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-15T16:07:22', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '85da7d2c-f1b8-4248-ba90-ac060b31070e' User entered 'None (0)'	System	15 Sep 2020 21:07:38
	System	15 Sep 2020 21:07:38

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-15T16:07:24', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '85da7d2c-f1b8-4248-ba90-ac060b31070e' User entered 'None (0)'	System	15 Sep 2020 21:07:38
	System	15 Sep 2020 21:07:38

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-15T16:07:25', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '85da7d2c-f1b8-4248-ba90-ac060b31070e' User entered 'None (0)'	System	15 Sep 2020 21:07:38
	System	15 Sep 2020 21:07:38

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-15T16:07:28', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '85da7d2c-f1b8-4248-ba90-ac060b31070e' User entered 'None (0)'	System	15 Sep 2020 21:07:38
	System	15 Sep 2020 21:07:38

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-15T16:07:29', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '85da7d2c-f1b8-4248-ba90-ac060b31070e' User entered 'None (0)'	System	15 Sep 2020 21:07:38
	System	15 Sep 2020 21:07:38

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-15T16:07:32', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '85da7d2c-f1b8-4248-ba90-ac060b31070e' User entered 'No (N)'	System	15 Sep 2020 21:07:38
	System	15 Sep 2020 21:07:38

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-09-15T16:07:34', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '85da7d2c-f1b8-4248-ba90-ac060b31070e' User entered '15 Sep 2020 16:07'	System	15 Sep 2020 21:07:38
	System	15 Sep 2020 21:07:38

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 17:39:22

US3212049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 17:39:22

US3212049

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:50:38
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	17 Sep 2020 14:46:08

US3212049

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:50:38
User entered '16 Sep 2020'	Laura Ngansop Djampou (b) (4)	17 Sep 2020 14:46:08

US3212049

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:50:38
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	17 Sep 2020 14:46:08

US3212049

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:50:38
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Sep 2020 14:46:08

US3212049

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:50:42
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	17 Sep 2020 14:46:15

US3212049

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'I'	System	17 Sep 2020 14:46:15

US3212049

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:52:35
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	24 Sep 2020 14:54:10

US3212049

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:52:35
User entered '23 Sep 2020'	Laura Ngansop Djampou (b) (4)	24 Sep 2020 14:54:10

US3212049

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:52:35
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	24 Sep 2020 14:54:10

US3212049

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:52:35
User entered empty.	Laura Ngansop Djampou (b) (4)	24 Sep 2020 14:54:10

US3212049

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 18:52:39
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	24 Sep 2020 14:54:19

US3212049

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'I'	System	24 Sep 2020 14:54:19

US3212049

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:45:29
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Oct 2020 13:53:32

US3212049

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:45:29
User entered '30 Sep 2020'	Laura Ngansop Djampou (b) (4)	01 Oct 2020 13:53:32

US3212049

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:45:29
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	01 Oct 2020 13:53:32

US3212049

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:45:29
User entered empty.	Laura Ngansop Djampou (b) (4)	01 Oct 2020 13:53:32

US3212049

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:45:46
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Oct 2020 13:53:37

US3212049

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'I'	System	01 Oct 2020 13:53:37

US3212049

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:15:30
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	06 Oct 2020 17:01:20

US3212049

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:35:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	09 Dec 2020 15:16:05
User entered '06 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	09 Dec 2020 15:16:05
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:15:30
User entered '6 Oct 2020'	Laura Ngansop Djampou (b) (4)	06 Oct 2020 17:01:20

US3212049

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:30

[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 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:15:30
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	06 Oct 2020 17:01:20

US3212049

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'VISIT3'	System	06 Oct 2020 17:01:20

US3212049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:15:51
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	06 Oct 2020 17:02:31

US3212049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:35:20
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	09 Dec 2020 15:16:11
User entered '06 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	09 Dec 2020 15:16:11
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:15:51
User entered '6 Oct 2020'	Laura Ngansop Djampou (b) (4)	06 Oct 2020 17:02:31

US3212049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:15:51
User entered '09:51'	Laura Ngansop Djampou (b) (4)	06 Oct 2020 17:02:31

US3212049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered '06 Oct 2020 09:51'	System	09 Dec 2020 15:16:11
User entered '6 Oct 2020 09:51'	System	06 Oct 2020 17:02:31

US3212049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:15:51
User entered '97.3' F	Laura Ngansop Djampou (b) (4)	06 Oct 2020 17:02:31

US3212049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:15:51
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	06 Oct 2020 17:02:31

US3212049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:15:51
User entered empty.	Laura Ngansop Djampou (b) (4)	06 Oct 2020 17:02:31

US3212049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:15:51
User entered '66'	Laura Ngansop Djampou (b) (4)	06 Oct 2020 17:02:31

US3212049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'bpm'	System	06 Oct 2020 17:02:31

US3212049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:15:51
User entered '16'	Laura Ngansop Djampou (b) (4)	06 Oct 2020 17:02:31

US3212049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'breaths/min'	System	06 Oct 2020 17:02:31

US3212049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:15:51
User entered '140'	Laura Ngansop Djampou (b) (4)	06 Oct 2020 17:02:31

US3212049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'mmHg'	System	06 Oct 2020 17:02:31

US3212049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:15:51
User entered '72'	Laura Ngansop Djampou (b) (4)	06 Oct 2020 17:02:31

US3212049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'mmHg'	System	06 Oct 2020 17:02:31

US3212049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13

US3212049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13

US3212049

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:15:59
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	06 Oct 2020 17:02:39

US3212049

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:35:25
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	09 Dec 2020 15:16:18
User entered '06 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	09 Dec 2020 15:16:18
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:15:59
User entered '6 Oct 2020'	Laura Ngansop Djampou (b) (4)	06 Oct 2020 17:02:39

US3212049

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:16:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	06 Oct 2020 17:02:54

US3212049

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:35:28
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	09 Dec 2020 15:16:26
User entered '06 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	09 Dec 2020 15:16:26
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:16:10
User entered '6 Oct 2020'	Laura Ngansop Djampou (b) (4)	06 Oct 2020 17:02:54

US3212049

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:16:10
User entered '10:20'	Laura Ngansop Djampou (b) (4)	06 Oct 2020 17:02:54

US3212049

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered '06 Oct 2020 10:20'	System	09 Dec 2020 15:16:26
User entered '6 Oct 2020 10:20'	System	06 Oct 2020 17:02:54

US3212049

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:16:15
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	06 Oct 2020 17:01:10

US3212049

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'I'	System	06 Oct 2020 17:01:10

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 64'	System	05 Aug 2020 18:40:59

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-10-06T07:42:52', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'e6177930-b528-41d8-bb2f-7b0fcd5af005'	System	06 Oct 2020 12:43:06
User entered 'No (N)'	System	06 Oct 2020 12:43:06

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Have you been exposed to someone with 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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-10-06T07:42:57', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'e6177930-b528-41d8-bb2f-7b0fcd5af005'	System	06 Oct 2020 12:43:06
User entered 'No (N)'	System	06 Oct 2020 12:43:06

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-10-06T07:43:03', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'e6177930-b528-41d8-bb2f-7b0fcd5af005' User entered '06 Oct 2020 07:43:03'	System	06 Oct 2020 12:43:06
	System	06 Oct 2020 12:43:06

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered '05 Oct 2020 00:01'	System	05 Aug 2020 18:40:59

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered '09 Oct 2020 23:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 71'	System	05 Aug 2020 18:40:59

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-10-12T10:41:59', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'f73d2409-da04-4b7e-a509-5998a3d4aacd' User entered 'No (N)'	System	12 Oct 2020 15:42:16
	System	12 Oct 2020 15:42:16

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Have you been exposed to someone with 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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-10-12T10:42:04', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'f73d2409-da04-4b7e-a509-5998a3d4aacd' User entered 'No (N)'	System	12 Oct 2020 15:42:16
	System	12 Oct 2020 15:42:16

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-10-12T10:42:13', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'f73d2409-da04-4b7e-a509-5998a3d4aacd' User entered '12 Oct 2020 10:42:13'	System	12 Oct 2020 15:42:16
	System	12 Oct 2020 15:42:16

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered '12 Oct 2020 00:01'	System	05 Aug 2020 18:40:59

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered '16 Oct 2020 23:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 78'	System	05 Aug 2020 18:40:59

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-10-19T17:06:40', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'a2483e03-fb4b-4dd9-9176-b33b6f4540cc' User entered 'No (N)'	System	19 Oct 2020 22:06:57
	System	19 Oct 2020 22:06:57

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

Have you been exposed to someone with 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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-10-19T17:06:51', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'a2483e03-fb4b-4dd9-9176-b33b6f4540cc'	System	19 Oct 2020 22:06:57
User entered 'No (N)'	System	19 Oct 2020 22:06:57

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-10-19T17:06:55', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'a2483e03-fb4b-4dd9-9176-b33b6f4540cc' User entered '19 Oct 2020 17:06:55'	System	19 Oct 2020 22:06:57
	System	19 Oct 2020 22:06:57

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered '19 Oct 2020 00:01'	System	05 Aug 2020 18:40:59

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered '23 Oct 2020 23:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 92'	System	05 Aug 2020 18:40:59

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-11-02T10:38:53', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '7635a024-03bc-4496-8ab2-de19b2e01bcb' User entered 'No (N)'	System	02 Nov 2020 16:39:05
	System	02 Nov 2020 16:39:05

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Have you been exposed to someone with 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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-11-02T10:38:57', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '7635a024-03bc-4496-8ab2-de19b2e01bcb' User entered 'No (N)'	System	02 Nov 2020 16:39:05
	System	02 Nov 2020 16:39:05

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-11-02T10:39:01', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '7635a024-03bc-4496-8ab2-de19b2e01bcb' User entered '02 Nov 2020 10:39:01'	System	02 Nov 2020 16:39:05
	System	02 Nov 2020 16:39:05

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered '02 Nov 2020 00:01'	System	05 Aug 2020 18:40:59

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered '06 Nov 2020 23:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 99'	System	05 Aug 2020 18:40:59

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-11-09T07:31:10', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '71d74706-f5c3-4c94-9d34-769193855a2a' User entered 'No (N)'	System	09 Nov 2020 13:31:27
	System	09 Nov 2020 13:31:27

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Have you been exposed to someone with 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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-11-09T07:31:19', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '71d74706-f5c3-4c94-9d34-769193855a2a' User entered 'No (N)'	System	09 Nov 2020 13:31:27
	System	09 Nov 2020 13:31:27

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-11-09T07:31:23', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '71d74706-f5c3-4c94-9d34-769193855a2a' User entered '09 Nov 2020 07:31:23'	System	09 Nov 2020 13:31:27
	System	09 Nov 2020 13:31:27

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered '09 Nov 2020 00:01'	System	05 Aug 2020 18:40:59

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered '13 Nov 2020 23:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered 'Day 106'	System	05 Aug 2020 18:40:59

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-11-16T00:01:58', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '676bcb40-588e-4b18-ade5-1ea5ca6ffc7c' User entered 'No (N)'	System	16 Nov 2020 06:02:20
	System	16 Nov 2020 06:02:20

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

Have you been exposed to someone with 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)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-11-16T00:02:09', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '676bcb40-588e-4b18-ade5-1ea5ca6ffc7c' User entered 'No (N)'	System	16 Nov 2020 06:02:20
	System	16 Nov 2020 06:02:20

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-11-16T00:02:16', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '676bcb40-588e-4b18-ade5-1ea5ca6ffc7c' User entered '16 Nov 2020 00:02:16'	System	16 Nov 2020 06:02:20
	System	16 Nov 2020 06:02:20

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered '16 Nov 2020 00:01'	System	05 Aug 2020 18:40:59

US3212049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:02:17
Data entry locked.	System	05 Aug 2020 18:40:59
User entered '20 Nov 2020 23:59'	System	05 Aug 2020 18:40:59

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-11-20T09:50:25', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'd29798d0-33db-4bd0-a01c-466ac1edf4a1' User entered 'No (N)'	System	20 Nov 2020 15:50:49
	System	20 Nov 2020 15:50:49

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

Have you been exposed to someone with 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-11-20T09:50:38', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'd29798d0-33db-4bd0-a01c-466ac1edf4a1'	System	20 Nov 2020 15:50:49
User entered 'No (N)'	System	20 Nov 2020 15:50:49

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-11-20T09:50:47', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'd29798d0-33db-4bd0-a01c-466ac1edf4a1' User entered '20 Nov 2020 09:50:47'	System	20 Nov 2020 15:50:49
	System	20 Nov 2020 15:50:49

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-11-27T09:03:36', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'fc04a9d9-4c9b-4b3a-bfb0-c10bf1879fa8' User entered 'No (N)'	System	27 Nov 2020 15:03:54
	System	27 Nov 2020 15:03:54

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Have you been exposed to someone with 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-11-27T09:03:45', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'fc04a9d9-4c9b-4b3a-bfb0-c10bf1879fa8' User entered 'No (N)'	System	27 Nov 2020 15:03:54

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-11-27T09:03:49', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'fc04a9d9-4c9b-4b3a-bfb0-c10bf1879fa8' User entered '27 Nov 2020 09:03:49'	System	27 Nov 2020 15:03:54
	System	27 Nov 2020 15:03:54

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-12-04T08:33:42', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'ee90aa2e-6a30-48f4-a85c-bb389d6c23f3'	System	08 Dec 2020 04:01:14
User entered 'No (N)'	System	08 Dec 2020 04:01:14

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

Have you been exposed to someone with 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-12-04T08:33:46', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'ee90aa2e-6a30-48f4-a85c-bb389d6c23f3'	System	08 Dec 2020 04:01:14
User entered 'No (N)'	System	08 Dec 2020 04:01:14

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-12-04T08:33:50', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'ee90aa2e-6a30-48f4-a85c-bb389d6c23f3' User entered '04 Dec 2020 08:33:50'	System	08 Dec 2020 04:01:14
	System	08 Dec 2020 04:01:14

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-12-11T08:02:12', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'b58c2d92-fb09-4a60-87d2-84d8a5e88238'	System	11 Dec 2020 14:02:34
User entered 'No (N)'	System	11 Dec 2020 14:02:34

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Have you been exposed to someone with 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-12-11T08:02:24', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'b58c2d92-fb09-4a60-87d2-84d8a5e88238' User entered 'No (N)'	System	11 Dec 2020 14:02:34
	System	11 Dec 2020 14:02:34

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-12-11T08:02:31', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'b58c2d92-fb09-4a60-87d2-84d8a5e88238' User entered '11 Dec 2020 08:02:31'	System	11 Dec 2020 14:02:34
	System	11 Dec 2020 14:02:34

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-12-18T00:01:27', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '0e584c13-e419-41bf-9f74-78a10e0d1f54'	System	18 Dec 2020 06:02:01
User entered 'No (N)'	System	18 Dec 2020 06:02:01

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Have you been exposed to someone with 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-12-18T00:01:31', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '0e584c13-e419-41bf-9f74-78a10e0d1f54'	System	18 Dec 2020 06:02:01
User entered 'No (N)'	System	18 Dec 2020 06:02:01

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-12-18T00:01:38', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '0e584c13-e419-41bf-9f74-78a10e0d1f54' User entered '18 Dec 2020 00:01:38'	System	18 Dec 2020 06:02:01
	System	18 Dec 2020 06:02:01

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-12-25T07:24:44', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3de1fa4b-9d9b-47ee-a722-28131730cb2c' User entered 'No (N)'	System	25 Dec 2020 14:24:56
	System	25 Dec 2020 14:24:56

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Have you been exposed to someone with 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-12-25T07:24:50', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3de1fa4b-9d9b-47ee-a722-28131730cb2c'	System	25 Dec 2020 14:24:56
User entered 'No (N)'	System	25 Dec 2020 14:24:56

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2020-12-25T07:24:53', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '3de1fa4b-9d9b-47ee-a722-28131730cb2c' User entered '25 Dec 2020 07:24:53'	System	25 Dec 2020 14:24:56
	System	25 Dec 2020 14:24:56

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-01-01T09:58:37', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '45d966c0-4958-40b2-88c9-83dc489bacaa' User entered 'No (N)'	System	01 Jan 2021 15:58:47
	System	01 Jan 2021 15:58:47

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

Have you been exposed to someone with 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-01-01T09:58:41', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '45d966c0-4958-40b2-88c9-83dc489bacaa' User entered 'No (N)'	System	01 Jan 2021 15:58:47
	System	01 Jan 2021 15:58:47

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-01-01T09:58:44', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '45d966c0-4958-40b2-88c9-83dc489bacaa' User entered '01 Jan 2021 09:58:44'	System	01 Jan 2021 15:58:47
	System	01 Jan 2021 15:58:47

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-01-08T00:02:04', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'e6ef51f6-ea18-4c99-a252-61184ea529ea' User entered 'No (N)'	System	08 Jan 2021 06:02:40
	System	08 Jan 2021 06:02:40

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Have you been exposed to someone with 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-01-08T00:02:12', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'e6ef51f6-ea18-4c99-a252-61184ea529ea'	System	08 Jan 2021 06:02:40
User entered 'No (N)'	System	08 Jan 2021 06:02:40

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-01-08T00:02:16', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'e6ef51f6-ea18-4c99-a252-61184ea529ea' User entered '08 Jan 2021 00:02:16'	System	08 Jan 2021 06:02:40
	System	08 Jan 2021 06:02:40

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-01-15T00:01:48', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '36ef4786-1c5d-4a5f-b41b-559027a70603'	System	15 Jan 2021 06:02:09
User entered 'No (N)'	System	15 Jan 2021 06:02:09

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Have you been exposed to someone with 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-01-15T00:01:51', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '36ef4786-1c5d-4a5f-b41b-559027a70603'	System	15 Jan 2021 06:02:09
User entered 'No (N)'	System	15 Jan 2021 06:02:09

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-01-15T00:01:56', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '36ef4786-1c5d-4a5f-b41b-559027a70603' User entered '15 Jan 2021 00:01:56'	System	15 Jan 2021 06:02:09
	System	15 Jan 2021 06:02:09

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-01-22T10:07:47', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'bde2836b-b85e-4ba1-a006-e9056c602ad2'	System	22 Jan 2021 16:12:11
User entered 'No (N)'	System	22 Jan 2021 16:12:11

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

Have you been exposed to someone with 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-01-22T10:07:49', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'bde2836b-b85e-4ba1-a006-e9056c602ad2'	System	22 Jan 2021 16:12:11
User entered 'No (N)'	System	22 Jan 2021 16:12:11

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-01-22T10:07:54', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'bde2836b-b85e-4ba1-a006-e9056c602ad2'	System	22 Jan 2021 16:12:11
User entered '22 Jan 2021 10:07:54'	System	22 Jan 2021 16:12:11

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-01-29T07:19:24', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '5b31d498-5336-4f94-9f28-ae1f7cce6eab' User entered 'No (N)'	System	29 Jan 2021 13:19:55
	System	29 Jan 2021 13:19:55

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

Have you been exposed to someone with 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-01-29T07:19:40', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '5b31d498-5336-4f94-9f28-ae1f7cce6eab' User entered 'No (N)'	System	29 Jan 2021 13:19:55
	System	29 Jan 2021 13:19:55

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-01-29T07:19:50', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '5b31d498-5336-4f94-9f28-ae1f7cce6eab' User entered '29 Jan 2021 07:19:50'	System	29 Jan 2021 13:19:55
	System	29 Jan 2021 13:19:55

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-02-05T06:12:47', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '4f35acfb-48e5-4fc7-96dd-d09f4ad2b2f1' User entered 'No (N)'	System	05 Feb 2021 12:13:41
	System	05 Feb 2021 12:13:41

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

Have you been exposed to someone with 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-02-05T06:13:13', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '4f35acfb-48e5-4fc7-96dd-d09f4ad2b2f1' User entered 'Yes (Y)'	System	05 Feb 2021 12:13:41
	System	05 Feb 2021 12:13:41

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Please 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-02-05T06:13:26', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '4f35acfb-48e5-4fc7-96dd-d09f4ad2b2f1'	System	05 Feb 2021 12:13:41
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Feb 2021 12:13:41

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-02-05T06:13:32', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '4f35acfb-48e5-4fc7-96dd-d09f4ad2b2f1' User entered '05 Feb 2021 06:13:32'	System	05 Feb 2021 12:13:41
	System	05 Feb 2021 12:13:41

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-02-12T00:01:57', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'e826b83e-68a9-41cd-8609-5da06f77d16e' User entered 'Yes (Y)'	System	12 Feb 2021 06:02:47
	System	12 Feb 2021 06:02:47

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Have you been exposed to someone with 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-02-12T00:02:02', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'e826b83e-68a9-41cd-8609-5da06f77d16e'	System	12 Feb 2021 06:02:47
User entered 'No (N)'	System	12 Feb 2021 06:02:47

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-02-12T00:02:07', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'e826b83e-68a9-41cd-8609-5da06f77d16e' User entered 'No (N)'	System	12 Feb 2021 06:02:47
	System	12 Feb 2021 06:02:47

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-02-12T00:02:18', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'e826b83e-68a9-41cd-8609-5da06f77d16e'	System	12 Feb 2021 06:02:47
User entered 'Yes (Y)'	System	12 Feb 2021 06:02:47

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Please 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-02-12T00:02:24', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'e826b83e-68a9-41cd-8609-5da06f77d16e'	System	12 Feb 2021 06:02:47
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Feb 2021 06:02:47

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-02-12T00:02:35', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'e826b83e-68a9-41cd-8609-5da06f77d16e' User entered '12 Feb 2021 00:02:35'	System	12 Feb 2021 06:02:47
	System	12 Feb 2021 06:02:47

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-02-19T08:22:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'f6d6de76-add7-418c-8342-b3f2002ccda2'	System	19 Feb 2021 14:22:09
User entered 'No (N)'	System	19 Feb 2021 14:22:09

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

Have you been exposed to someone with 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-02-19T08:22:04', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'f6d6de76-add7-418c-8342-b3f2002ccda2'	System	19 Feb 2021 14:22:09
User entered 'No (N)'	System	19 Feb 2021 14:22:09

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-02-19T08:22:07', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'f6d6de76-add7-418c-8342-b3f2002ccda2' User entered '19 Feb 2021 08:22:07'	System	19 Feb 2021 14:22:09
	System	19 Feb 2021 14:22:09

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-02-26T07:43:22', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'ae46b650-25e7-47d3-83b5-1dd17d721ae5' User entered 'No (N)'	System	26 Feb 2021 13:43:35
	System	26 Feb 2021 13:43:35

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

Have you been exposed to someone with 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-02-26T07:43:26', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'ae46b650-25e7-47d3-83b5-1dd17d721ae5' User entered 'No (N)'	System	26 Feb 2021 13:43:35

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-02-26T07:43:30', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'ae46b650-25e7-47d3-83b5-1dd17d721ae5' User entered '26 Feb 2021 07:43:30'	System	26 Feb 2021 13:43:35
	System	26 Feb 2021 13:43:35

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-03-05T00:02:44-06:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '20c15043-99fc-4714-8793-d72c1a12a3a7'	System	05 Mar 2021 06:02:53
User entered 'No (N)'	System	05 Mar 2021 06:02:53

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

Have you been exposed to someone with 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-03-05T00:02:47-06:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '20c15043-99fc-4714-8793-d72c1a12a3a7'	System	05 Mar 2021 06:02:53
User entered 'No (N)'	System	05 Mar 2021 06:02:53

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-03-05T00:02:50-06:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '20c15043-99fc-4714-8793-d72c1a12a3a7'	System	05 Mar 2021 06:02:53
User entered '05 Mar 2021 06:02:50'	System	05 Mar 2021 06:02:53

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-03-12T07:16:08-06:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '6a686e8f-2eef-4be2-97cf-06839e34af98'	System	12 Mar 2021 13:16:22
User entered 'No (N)'	System	12 Mar 2021 13:16:22

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Have you been exposed to someone with 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-03-12T07:16:11-06:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '6a686e8f-2eef-4be2-97cf-06839e34af98'	System	12 Mar 2021 13:16:22
User entered 'No (N)'	System	12 Mar 2021 13:16:22

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-03-12T07:16:18-06:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '6a686e8f-2eef-4be2-97cf-06839e34af98'	System	12 Mar 2021 13:16:22
User entered '12 Mar 2021 13:16:18'	System	12 Mar 2021 13:16:22

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-03-21T11:08:40-05:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'c742d757-34bf-4b62-a0f8-2e8801aaa3c6'	System	21 Mar 2021 16:11:08
User entered 'No (N)'	System	21 Mar 2021 16:11:08

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

Have you been exposed to someone with 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-03-21T11:08:42-05:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'c742d757-34bf-4b62-a0f8-2e8801aaa3c6'	System	21 Mar 2021 16:11:08
User entered 'No (N)'	System	21 Mar 2021 16:11:08

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-03-21T11:08:45-05:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'c742d757-34bf-4b62-a0f8-2e8801aaa3c6'	System	21 Mar 2021 16:11:08
User entered '21 Mar 2021 11:08:45'	System	21 Mar 2021 16:11:08

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-03-26T07:00:52-05:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '7f2d61a8-8caa-4bdf-aed7-75bdee07b19c'	System	26 Mar 2021 12:01:05
User entered 'No (N)'	System	26 Mar 2021 12:01:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

Have you been exposed to someone with 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-03-26T07:00:55-05:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '7f2d61a8-8caa-4bdf-aed7-75bdee07b19c'	System	26 Mar 2021 12:01:05
User entered 'No (N)'	System	26 Mar 2021 12:01:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-03-26T07:00:58-05:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '7f2d61a8-8caa-4bdf-aed7-75bdee07b19c' User entered '26 Mar 2021 07:00:58'	System	26 Mar 2021 12:01:05
	System	26 Mar 2021 12:01:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-04-02T07:25:36-05:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '33070c10-5c07-4e3b-ad05-ced03349ed6b' User entered 'No (N)'	System	02 Apr 2021 12:25:46
	System	02 Apr 2021 12:25:46

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

Have you been exposed to someone with 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-04-02T07:25:41-05:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '33070c10-5c07-4e3b-ad05-ced03349ed6b' User entered 'No (N)'	System	02 Apr 2021 12:25:46

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-04-02T07:25:44-05:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '33070c10-5c07-4e3b-ad05-ced03349ed6b' User entered '02 Apr 2021 07:25:44'	System	02 Apr 2021 12:25:46
	System	02 Apr 2021 12:25:46

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-04-09T07:50:52-05:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '421a5b19-620c-4b5d-9ffe-911d7ceeeb09'	System	09 Apr 2021 12:51:04
User entered 'No (N)'	System	09 Apr 2021 12:51:04

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Have you been exposed to someone with 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-04-09T07:50:56-05:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '421a5b19-620c-4b5d-9ffe-911d7ceeb09'	System	09 Apr 2021 12:51:04
User entered 'No (N)'	System	09 Apr 2021 12:51:04

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-04-09T07:50:59-05:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '421a5b19-620c-4b5d-9ffe-911d7ceeeb09'	System	09 Apr 2021 12:51:04
User entered '09 Apr 2021 07:50:59'	System	09 Apr 2021 12:51:04

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-04-16T07:24:17-05:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '4782e96d-eb4d-44d9-992c-050ed40298b8'	System	16 Apr 2021 12:24:25
User entered 'No (N)'	System	16 Apr 2021 12:24:25

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Have you been exposed to someone with 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-04-16T07:24:20-05:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '4782e96d-eb4d-44d9-992c-050ed40298b8'	System	16 Apr 2021 12:24:25
User entered 'No (N)'	System	16 Apr 2021 12:24:25

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-04-16T07:24:23-05:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '4782e96d-eb4d-44d9-992c-050ed40298b8'	System	16 Apr 2021 12:24:25
User entered '16 Apr 2021 07:24:23'	System	16 Apr 2021 12:24:25

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-04-23T07:01:53-05:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '58874346-1bee-4949-bd9c-894dbe783724'	System	23 Apr 2021 12:02:07
User entered 'No (N)'	System	23 Apr 2021 12:02:07

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

Have you been exposed to someone with 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-04-23T07:01:57-05:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '58874346-1bee-4949-bd9c-894dbe783724'	System	23 Apr 2021 12:02:07
User entered 'No (N)'	System	23 Apr 2021 12:02:07

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-04-23T07:02:01-05:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '58874346-1bee-4949-bd9c-894dbe783724'	System	23 Apr 2021 12:02:07
User entered '23 Apr 2021 07:02:01'	System	23 Apr 2021 12:02:07

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-04-30T00:02:44-05:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'd6762e8c-d60e-49ca-a1ae-3fe152cd2610'	System	30 Apr 2021 05:02:53
User entered 'No (N)'	System	30 Apr 2021 05:02:53

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Have you been exposed to someone with 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 (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-04-30T00:02:46-05:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'd6762e8c-d60e-49ca-a1ae-3fe152cd2610'	System	30 Apr 2021 05:02:53
User entered 'No (N)'	System	30 Apr 2021 05:02:53

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-04-30T00:02:49-05:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: 'd6762e8c-d60e-49ca-a1ae-3fe152cd2610'	System	30 Apr 2021 05:02:53
User entered '30 Apr 2021 00:02:49'	System	30 Apr 2021 05:02:53

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 13:35:05

US3212049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:46:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:35:05
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 13:35:05

US3212049

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:46:30

[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 07:44:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-03-05T00:02:29-06:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '364c8969-b3a1-4153-beae-b115c75354e2'	System	05 Mar 2021 06:02:45
User entered 'No (N)'	System	05 Mar 2021 06:02:45

US3212049

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:46:30

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:44:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9151F5CA-153F-4D31-94AA-F007448C11AA)', Time: '2021-03-05T00:02:38-06:00', User OID: 'PatientReportedOutcome (US3212049)', ODM File OID: '364c8969-b3a1-4153-beae-b115c75354e2' User entered '05 Mar 2021 06:02:38'	System	05 Mar 2021 06:02:45
	System	05 Mar 2021 06:02:45

US3212049

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 15:58:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Nov 2020 14:37:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	29 Oct 2020 14:41:34

US3212049

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 15:58:08
User entered '03 Nov 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	02 Dec 2020 20:37:47
User entered '3 Nov 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Nov 2020 14:37:10
User entered empty.	Laura Ngansop Djampou (b) (4)	29 Oct 2020 14:41:34

US3212049

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 15:58:08
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Nov 2020 14:37:10
User entered empty.	Laura Ngansop Djampou (b) (4)	29 Oct 2020 14:41:34

US3212049

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 15:58:08
User entered empty.	Laura Ngansop Djampou (b) (4)	29 Oct 2020 14:41:34

US3212049

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:55:28
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 15:58:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 14:37:19

US3212049

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'I'	System	04 Nov 2020 14:37:19

US3212049

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:37:13
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	09 Dec 2020 15:14:34

US3212049

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:37:13
User entered '08 Dec 2020'	Laura Ngansop Djampou (b) (4)	09 Dec 2020 15:14:34

US3212049

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:37:13
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	09 Dec 2020 15:14:34

US3212049

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:37:13
User entered empty.	Laura Ngansop Djampou (b) (4)	09 Dec 2020 15:14:34

US3212049

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:37:18
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	09 Dec 2020 15:14:38

US3212049

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'I'	System	09 Dec 2020 15:14:38

US3212049

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:37:55
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	05 Jan 2021 21:17:59

US3212049

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:37:55
User entered '05 Jan 2021'	Afifah Ayub (b) (4)	05 Jan 2021 21:17:59

US3212049

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:37:55
User entered 'Contact Made (CONTACT MADE)'	Afifah Ayub (b) (4)	05 Jan 2021 21:17:59

US3212049

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:37:55
User entered empty.	Afifah Ayub (b) (4)	05 Jan 2021 21:17:59

US3212049

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:32:59
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	05 Jan 2021 21:18:05

US3212049

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'I'	System	05 Jan 2021 21:18:05

US3212049

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:36:40
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 14:38:22

US3212049

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:36:40
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered '05 Feb 2021'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 14:38:22

US3212049

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:36:40
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 14:38:22

US3212049

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:36:40
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 14:38:22

US3212049

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:37:08
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 14:38:26

US3212049

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'I'	System	08 Feb 2021 14:38:26

US3212049

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:37:55
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	26 Feb 2021 14:34:18

US3212049

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:37:55
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered '24 Feb 2021'	Laura Ngansop Djampou (b) (4)	26 Feb 2021 14:34:18

US3212049

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:30

[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 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:37:55
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	26 Feb 2021 14:34:18

US3212049

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:46:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'VISIT4'	System	26 Feb 2021 14:34:18

US3212049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:38:13
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 16:43:57

US3212049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:38:13
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered '24 Feb 2021'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 16:43:57

US3212049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:38:13
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered '10:00'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 16:43:57

US3212049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered '24 Feb 2021 10:00'	System	30 Mar 2021 16:43:57

US3212049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:38:13
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered '97.7' F	Laura Ngansop Djampou (b) (4)	30 Mar 2021 16:43:57

US3212049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:38:13
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 16:43:57

US3212049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:38:13
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered empty.	Laura Ngansop Djampou (b) (4)	30 Mar 2021 16:43:57

US3212049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:38:13
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered '74'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 16:43:57

US3212049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'bpm'	System	30 Mar 2021 16:43:57

US3212049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:38:13
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered '16'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 16:43:57

US3212049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'breaths/min'	System	30 Mar 2021 16:43:57

US3212049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:38:13
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered '134'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 16:43:57

US3212049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'mmHg'	System	30 Mar 2021 16:43:57

US3212049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:38:13
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered '74'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 16:43:57

US3212049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'mmHg'	System	30 Mar 2021 16:43:57

US3212049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13

US3212049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:46:30

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13

US3212049

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:38:23
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 16:15:27

US3212049

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:46:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:38:23
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered '24 Feb 2021'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 16:15:27

US3212049

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:38:30
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 16:14:46

US3212049

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:38:30
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	01 Mar 2021 16:15:09
User entered '24 Feb 2021' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	01 Mar 2021 16:15:09
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	01 Mar 2021 16:14:46
User entered '26 Feb 2021'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 16:14:46

US3212049

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:38:30
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered '10:27'	(b) (4) Laura Ngansop Djampou (b) (4)	01 Mar 2021 16:14:46

US3212049

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered '24 Feb 2021 10:27'	System	01 Mar 2021 16:15:09
User entered '26 Feb 2021 10:27'	System	01 Mar 2021 16:14:46

US3212049

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:41:11
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 16:15:33

US3212049

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:34:13
User entered 'I'	System	01 Mar 2021 16:15:33

US3212049

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:24
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	08 Apr 2021 14:00:17

US3212049

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:24
User entered '06 Apr 2021'	Laura Ngansop Djampou (b) (4)	08 Apr 2021 14:00:17

US3212049

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:24
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	08 Apr 2021 14:00:17

US3212049

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:46:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:24
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Apr 2021 14:00:17

US3212049

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:24
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	08 Apr 2021 14:00:02

US3212049

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:46:30

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 14:00:02

US3212049

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

Form: Visit Date

Generated On: 09 Jun 2021 15:46:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:22
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:41:48
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	14 Jan 2021 21:21:29

US3212049

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

Form: Visit Date

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:22
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:41:48
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered '14 Jan 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	14 Jan 2021 21:21:29

US3212049

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

Form: Visit Date

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:22
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:41:48
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	14 Jan 2021 21:21:29

US3212049

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

Form: Visit Date

Generated On: 09 Jun 2021 15:46:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:22
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 21:21:29

US3212049

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:30

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:22
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:42:54
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered '14 Jan 2021'	Laura Ngansop Djampou (b) (4)	14 Jan 2021 21:21:56

US3212049

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:30

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:22
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:24:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:10:08
User entered '0'	Heather Leary (b) (4)	22 Apr 2021 14:28:45
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 02:24:58

US3212049

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:30

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:22
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:42:54
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	14 Jan 2021 21:21:56

US3212049

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:30

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:22
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). User signature succeeded.	(b) (4), (b) (6)	23 Apr 2021 14:34:19
DataPoint Verified.	Insiya Valika (b) (4)	22 Apr 2021 19:24:36
	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 18:10:04
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 14:29:01
	(b) (4)	
User entered 'Amendment 6 or later (Amendment 6 or later)'	Heather Leary (b) (4)	22 Apr 2021 14:28:45
	(b) (4)	
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 05:46:30
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:24:58

US3212049

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:30

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:22
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:42:54
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered '14 Jan 2021'	Laura Ngansop Djampou (b) (4)	14 Jan 2021 21:21:56

US3212049

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:30

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:22
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:42:54
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered 'mRNA-1273 (mRNA-1273)'	Laura Ngansop Djampou (b) (4)	14 Jan 2021 21:21:56

US3212049

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:30

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:22
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:42:54
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	
System		20 Jan 2021 01:14:33
User entered 'mRNA-1273 (mRNA-1273)'	Laura Ngansop Djampou	14 Jan 2021 21:21:56
	(b) (4)	

US3212049

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:30

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:22
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:42:54
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	
System		20 Jan 2021 01:14:33
User entered 'mRNA-1273 (mRNA-1273)'	Laura Ngansop Djampou	14 Jan 2021 21:21:56
	(b) (4)	

US3212049

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:30

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:22
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:42:54
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	14 Jan 2021 21:21:56

US3212049

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:30

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:22
User entered empty.	System	14 Jan 2021 21:21:56

US3212049

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

Form: Unblinding

Generated On: 09 Jun 2021 15:46:30

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:22
User entered empty.	System	14 Jan 2021 21:21:56

US3212049

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:22
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:43:14
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	14 Jan 2021 21:22:14

US3212049

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:22
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:43:14
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered '14 Jan 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	14 Jan 2021 21:22:14

US3212049

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:22
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:43:14
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered '14:26'	(b) (4) Laura Ngansop Djampou (b) (4)	14 Jan 2021 21:22:14

US3212049

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:22
User entered '14 Jan 2021 14:26'	System	14 Jan 2021 21:22:14

US3212049

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:46:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:22
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:43:24
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	14 Jan 2021 21:22:25

US3212049

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:46:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:22
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:43:24
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered '14 Jan 2021'	Laura Ngansop Djampou (b) (4)	14 Jan 2021 21:22:25

US3212049

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:46:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:22
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:43:24
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered '14:23'	Laura Ngansop Djampou (b) (4)	14 Jan 2021 21:22:25

US3212049

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:53:22
User entered '14 Jan 2021 14:23'	System	14 Jan 2021 21:22:25

US3212049

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:46:30

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:27:55
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:45:02
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:54:14
DataPoint Un-verified.	Afifah Ayub (b) (4)	13 Dec 2020 19:24:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	13 Dec 2020 19:24:29
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 19:00:53
User entered 'No (N)'	Afifah Ayub (b) (4)	10 Sep 2020 19:09:27

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:45:17
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Conjunctivitis bacterial, LLT: Conjunctivitis bacterial - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Dec 2020 19:26:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Dec 2020 19:26:28
Data point term sent to Coder	System	13 Dec 2020 19:25:09
User entered 'Bilateral bacterial conjunctivitis'	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:45:19
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:45:23
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:45:25
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:45:29
User entered '30 Nov 2020'	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:45:32
User entered empty.	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:45:39
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:45:41
User entered empty.	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:45:42
User entered empty.	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:45:44
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Afifah Ayub (b) (4)	13 Dec 2020 19:25:06
	(b) (4)	

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:45:46
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:45:49
User entered '0'	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:45:52
User entered '0'	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:45:54
User entered '0'	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:45:55
User entered empty.	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:45:58
User entered empty.	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:46:00
User entered empty.	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:46:02
User entered empty.	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:46:04
User entered '0'	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:46:05
User entered '0'	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:46:07
User entered '0'	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:46:13
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:46:15
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:46:18
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Dec 2020 19:25:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Dec 2020 19:25:28
User entered 'None (NONE)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	13 Dec 2020 19:25:28
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Dec 2020 19:25:06
User entered empty.	Afifah Ayub (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:46:20
User entered '0'	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:46:22
User entered '1'	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:46:24
User entered '0'	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:46:25
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:46:28
User entered empty.	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:46:30
User entered empty.	Afifah Ayub (b) (4) (b) (4)	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:46:30

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Dec 2020 19:25:06

US3212049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:46:39
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:44:51
User entered 'USA-US115-2021-mRNA-1273-P301000015'	System	25 Feb 2021 16:48:03
User entered 'New'	(b) (4), (b) (6)	25 Feb 2021 16:48:03

US3212049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:46:41
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 18:28:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 18:28:59
Data point term sent to Coder	System	24 Feb 2021 18:12:53
User entered 'prostate cancer'	Heather Leary (b) (4) (b) (4)	24 Feb 2021 18:12:01

US3212049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:46:43
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	24 Feb 2021 18:12:01

US3212049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:35
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	24 Feb 2021 18:12:01

US3212049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:47:32
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	24 Feb 2021 18:12:01

US3212049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User entered '01 Feb 2021' reason for change: Data Entry Error	Heather Leary (b) (4)	24 Feb 2021 20:27:01
User entered '1 Feb 2021'	Heather Leary (b) (4)	24 Feb 2021 18:12:01

US3212049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:47:41
User entered empty.	Heather Leary (b) (4) (b) (4)	24 Feb 2021 18:12:01

US3212049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 18:12:01

US3212049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:47:42
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	24 Feb 2021 18:12:01

US3212049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:47:44
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)	05 Mar 2021 05:29:49
User entered empty.	Heather Leary (b) (4) (b) (4)	24 Feb 2021 18:12:01

US3212049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:47:53
User entered empty.	Heather Leary (b) (4) (b) (4)	24 Feb 2021 18:12:01

US3212049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 18:12:01

US3212049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:47:56
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 20:16:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 20:16:19
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Heather Leary (b) (4)	24 Feb 2021 20:16:19
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 18:12:01
User entered empty.	Heather Leary (b) (4)	24 Feb 2021 18:12:01

US3212049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:47:58
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 20:16:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 20:16:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Leary (b) (4)	24 Feb 2021 20:16:19
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 18:12:01
User entered empty.	Heather Leary (b) (4)	24 Feb 2021 18:12:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:48:05
User entered '0'	Heather Leary (b) (4) (b) (4)	24 Feb 2021 18:12:01

US3212049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:48:07
User entered '0'	Heather Leary (b) (4) (b) (4)	24 Feb 2021 18:12:01

US3212049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:48:09
User entered '0'	Heather Leary (b) (4) (b) (4)	24 Feb 2021 18:12:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:48:12
User entered empty.	Heather Leary (b) (4) (b) (4)	24 Feb 2021 18:12:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:48:14
User entered empty.	Heather Leary (b) (4) (b) (4)	24 Feb 2021 18:12:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:48:16
User entered empty.	Heather Leary (b) (4) (b) (4)	24 Feb 2021 18:12:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:48:18
User entered empty.	Heather Leary (b) (4) (b) (4)	24 Feb 2021 18:12:01

US3212049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:48:19
User entered '0'	Heather Leary (b) (4) (b) (4)	24 Feb 2021 18:12:01

US3212049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:48:21
User entered '0'	Heather Leary (b) (4) (b) (4)	24 Feb 2021 18:12:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:48:22
User entered '1' reason for change: Data Entry Error	Heather Leary (b) (4)	24 Feb 2021 20:16:19
User entered '0'	Heather Leary (b) (4)	24 Feb 2021 18:12:01

US3212049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:30:41
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product must be "Related" or "Not Related". Please update the CRF accordingly. ' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 12:39:38
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product must be "Related" or "Not Related". Please update the CRF accordingly. ' answered with 'updated' (Site from Safety).	Reagan Reed (b) (4)	08 Mar 2021 14:50:10
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4)	08 Mar 2021 14:50:00
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product must be "Related" or "Not Related". Please update the CRF accordingly. ' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 05:24:58
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 20:16:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 20:16:19
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Heather Leary (b) (4)	24 Feb 2021 20:16:19
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 18:12:01
User entered empty.	Heather Leary (b) (4)	24 Feb 2021 18:12:01

US3212049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please update relatedness to study procedure. As subject received the study drug, relatedness to study procedure should be reported as related or not related.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 17:21:12
User closed query 'Per source, 'Not related'. Please verify and update accordingly.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 22:15:46
	(b) (4), (b) (6)	19 Apr 2021 22:15:34
Query 'Per source, 'Not related'. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Heather Leary (b) (4)	19 Apr 2021 19:20:44
Query 'PV Query: Please update relatedness to study procedure. As subject received the study drug, relatedness to study procedure should be reported as related or not related.' answered with 'updated' (Site from Safety).	Heather Leary (b) (4)	19 Apr 2021 19:19:52
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Heather Leary (b) (4)	19 Apr 2021 19:19:21
User opened query 'Per source, 'Not related'. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:31:16
User opened query 'PV Query: Please update relatedness to study procedure. As subject received the study drug, relatedness to study procedure should be reported as related or not related.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 23:20:21
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Apr 2021 15:33:14
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 12:40:09
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly' answered with 'updated' (Site from Safety).	Reagan Reed (b) (4)	08 Mar 2021 14:50:15
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Reagan Reed (b) (4)	08 Mar 2021 14:50:00

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 05:25:39
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 20:16:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 20:16:19
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Heather Leary (b) (4)	24 Feb 2021 20:16:19
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 18:12:01
User entered empty.	Heather Leary (b) (4)	24 Feb 2021 18:12:01

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Folder: Adverse Events

Form: Adverse Events (2)

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Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: Please change action taken with study drug from none to not applicable as subject received both scheduled doses.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 17:22:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 22:15:59
Query 'PV Query: Please change action taken with study drug from none to not applicable as subject received both scheduled doses.' answered with 'updated' (Site from Safety).	Heather Leary (b) (4)	19 Apr 2021 19:21:06
DataPoint Un-verified.	Heather Leary (b) (4)	19 Apr 2021 19:20:25
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Heather Leary (b) (4)	19 Apr 2021 19:20:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:31:23
User opened query 'PV Query: Please change action taken with study drug from none to not applicable as subject received both scheduled doses.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 23:20:08
User entered 'None (NONE)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Apr 2021 15:32:38
User closed query ' PV Query: Since the subject received both scheduled doses of the study drug prior to the event onset, please consider updating the action taken from "None" to "Not applicable". ' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 12:40:30
Query ' PV Query: Since the subject received both scheduled doses of the study drug prior to the event onset, please consider updating the action taken from "None" to "Not applicable". ' answered with 'updated' (Site from Safety).	Reagan Reed (b) (4)	08 Mar 2021 14:50:20
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Reagan Reed (b) (4)	05 Mar 2021 16:12:20
User opened query ' PV Query: Since the subject received both scheduled doses of the study drug prior to the event onset, please consider updating the action taken from "None" to "Not applicable". ' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 05:24:17
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 20:16:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 20:16:19
User entered 'None (NONE)' reason for change: Data Entry Error	Heather Leary (b) (4)	24 Feb 2021 20:16:19
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 18:12:01
User entered empty.	Heather Leary (b) (4)	24 Feb 2021 18:12:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:56:24
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	24 Feb 2021 20:16:19
User entered '1' reason for change: Data Entry Error	Heather Leary (b) (4)	24 Feb 2021 20:16:19
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	24 Feb 2021 18:12:01
User entered '0'	Heather Leary (b) (4)	24 Feb 2021 18:12:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:56:26
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 14:44:39
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'No treatment provided at this time, will update if there are changes' (Site from Safety).	Reagan Reed (b) (4) (b) (4)	08 Mar 2021 14:50:44
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 05:26:13
User entered '0'	Heather Leary (b) (4) (b) (4)	24 Feb 2021 18:12:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:56:28
User closed 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.	(b) (4), (b) (6)	09 Mar 2021 14:44:44
' (Site from Safety). 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.	Reagan Reed (b) (4) (b) (4)	08 Mar 2021 14:50:49
' answered with 'No treatment provided at this time, will update if there are changes' (Site from Safety). 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.	(b) (4), (b) (6)	05 Mar 2021 05:32:12
' (Site from Safety). User entered '0'	Heather Leary (b) (4) (b) (4)	24 Feb 2021 18:12:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:56:31
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)	05 Mar 2021 05:28:29
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Heather Leary (b) (4) (b) (4)	24 Feb 2021 18:12:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:56:34
User entered empty.	Heather Leary (b) (4) (b) (4)	24 Feb 2021 18:12:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[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. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 23:19:58
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 23:19:36
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:56:36
User entered 'SUBJECT IS DIAGNOSED WITH PROSTATE CANCER' reason for change: Data Entry Error	Heather Leary (b) (4)	24 Feb 2021 20:16:19
User entered empty.	Heather Leary (b) (4)	24 Feb 2021 18:12:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Feb 2021 20:16:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:46:30

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Feb 2021 18:12:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:46:30

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:27:55
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:56:44
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered 'Yes (Y)'	Heather Leary (b) (4)	05 Aug 2020 17:55:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:55:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 17:57:00
User coded data point as Term Coded data point by	(b) (4)	
User: Coder System - version	(b) (4)	05 Aug 2020 17:57:00
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	05 Aug 2020 17:56:36
User entered 'Atorvastatin'	Heather Leary (b) (4)	05 Aug 2020 17:56:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:55:11
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:56:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:55:09
User entered 'Hypercholesterolemia'	Heather Leary (b) (4)	05 Aug 2020 17:56:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:55:07
User entered '20'	Heather Leary (b) (4)	05 Aug 2020 17:56:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:55:06
User entered 'mg (mg)'	Heather Leary (b) (4)	05 Aug 2020 17:56:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:30

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:55:04
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 17:56:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:55:03
User entered 'once daily (QD)'	Heather Leary (b) (4)	05 Aug 2020 17:56:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:55:01
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 17:56:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:54:59
User entered 'Oral (ORAL)'	Heather Leary (b) (4)	05 Aug 2020 17:56:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:54:58
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 17:56:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:54:56
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 02:40:33
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Subject is currently on the medication.' (Site from System).	Afifah Ayub (b) (4)	05 Aug 2020 18:46:38
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 18:40:59
User entered 'un UNK 2010'	Heather Leary (b) (4)	05 Aug 2020 17:56:02
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:54:53
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 17:56:02
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:54:51
User entered 'Yes (Y)'	Heather Leary (b) (4)	05 Aug 2020 17:56:02
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:54:50
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 17:56:02
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:54:48
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:56:02
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 17:56:02

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 17:56:02

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:46:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 17:56:02

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:56:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 17:59:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 17:59:58
Data point term sent to Coder	System	05 Aug 2020 17:58:36
User entered 'Omeprazole'	Heather Leary (b) (4)	05 Aug 2020 17:57:51
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:56:14
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:57:51
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:56:09
User entered 'Gastroesophageal reflux disease'	Heather Leary (b) (4)	05 Aug 2020 17:57:51
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:56:11
User entered '20'	Heather Leary (b) (4)	05 Aug 2020 17:57:51
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:56:05
User entered 'mg (mg)'	Heather Leary (b) (4)	05 Aug 2020 17:57:51
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:30

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:56:03
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 17:57:51
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:56:02
User entered 'once daily (QD)'	Heather Leary (b) (4)	05 Aug 2020 17:57:51
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:56:00
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 17:57:51
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:55:58
User entered 'Oral (ORAL)'	Heather Leary (b) (4)	05 Aug 2020 17:57:51
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:55:57
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 17:57:51
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:55:55
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 02:40:40
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Subject is currently on the medication.' (Site from System).	Afifah Ayub (b) (4)	05 Aug 2020 18:46:48
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 18:40:59
User entered 'un UNK 2010'	Heather Leary (b) (4)	05 Aug 2020 17:57:51
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:55:51
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 17:57:51
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:55:50
User entered 'Yes (Y)'	Heather Leary (b) (4)	05 Aug 2020 17:57:51
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:55:48
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 17:57:51
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:55:46
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:57:51
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 17:57:51

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 17:57:51

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:46:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 17:57:51

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:56:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 17:59:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 17:59:58
Data point term sent to Coder	System	05 Aug 2020 17:58:36
User entered 'Lisinopril'	Heather Leary (b) (4)	05 Aug 2020 17:58:32
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:56:32
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:58:32
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:56:34
User entered 'Hypertension'	Heather Leary (b) (4)	05 Aug 2020 17:58:32
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:56:35
User entered '20'	Heather Leary (b) (4)	05 Aug 2020 17:58:32
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:56:37
User entered 'mg (mg)'	Heather Leary (b) (4)	05 Aug 2020 17:58:32
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:30

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:56:38
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 17:58:32
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:56:40
User entered 'once daily (QD)'	Heather Leary (b) (4)	05 Aug 2020 17:58:32
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:56:43
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 17:58:32
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:56:46
User entered 'Oral (ORAL)'	Heather Leary (b) (4)	05 Aug 2020 17:58:32
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:30

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:56:48
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 17:58:32
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:56:51
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 02:40:47
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Subject is currently on the medication.' (Site from System).	Afifah Ayub (b) (4)	05 Aug 2020 18:46:59
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 18:40:59
User entered 'un UNK 2010'	Heather Leary (b) (4)	05 Aug 2020 17:58:32
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:56:55
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 17:58:32
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:56:57
User entered 'Yes (Y)'	Heather Leary (b) (4)	05 Aug 2020 17:58:32
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:57:00
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 17:58:32
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:57:02
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:58:32
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 17:58:32

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 17:58:32

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:46:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 17:58:32

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:58:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 20:46:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 20:46:04
Data point term sent to Coder	System	05 Aug 2020 17:59:37
User entered 'Vitamin D'	Heather Leary (b) (4)	05 Aug 2020 17:59:21
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:58:13
User entered 'Yes (Y)'	Heather Leary (b) (4)	05 Aug 2020 17:59:21
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:58:07
User entered 'General health'	Heather Leary (b) (4)	05 Aug 2020 17:59:21
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:58:04
User entered '2000'	Heather Leary (b) (4)	05 Aug 2020 17:59:21
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:58:02
User entered 'IU (IU)'	Heather Leary (b) (4)	05 Aug 2020 17:59:21
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:58:00
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 17:59:21
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:57:57
User entered 'once daily (QD)'	Heather Leary (b) (4)	05 Aug 2020 17:59:21
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:57:53
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 17:59:21
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:57:55
User entered 'Oral (ORAL)'	Heather Leary (b) (4)	05 Aug 2020 17:59:21
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:30

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:57:51
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 17:59:21
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:57:49
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 02:40:54
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Subject is currently on the medication.' (Site from System).	Afifah Ayub (b) (4)	05 Aug 2020 18:47:11
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 18:40:59
User entered 'un UNK 2010'	Heather Leary (b) (4)	05 Aug 2020 17:59:21
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:57:48
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 17:59:21
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:57:47
User entered 'Yes (Y)'	Heather Leary (b) (4)	05 Aug 2020 17:59:21
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:57:45
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 17:59:21
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:57:43
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 17:59:21
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 17:59:21

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 17:59:21

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:46:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 17:59:21

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:59:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 18:04:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 18:04:11
Data point term sent to Coder	System	05 Aug 2020 18:02:41
User entered 'Multivitamin'	Heather Leary (b) (4)	05 Aug 2020 18:01:59
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:59:12
User entered 'Yes (Y)'	Heather Leary (b) (4)	05 Aug 2020 18:01:59
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:59:10
User entered 'General health'	Heather Leary (b) (4)	05 Aug 2020 18:01:59
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:59:08
User entered 'I'	Heather Leary (b) (4)	05 Aug 2020 18:01:59
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:59:06
User entered 'tablet (TABLET)'	Heather Leary (b) (4)	05 Aug 2020 18:01:59
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:59:05
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 18:01:59
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:59:03
User entered 'once daily (QD)'	Heather Leary (b) (4)	05 Aug 2020 18:01:59
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:59:02
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 18:01:59
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:59:00
User entered 'Oral (ORAL)'	Heather Leary (b) (4)	05 Aug 2020 18:01:59
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:30

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:58:59
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 18:01:59
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:58:57
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 02:41:04
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Subject is currently on the medication.' (Site from System).	Afifah Ayub (b) (4)	05 Aug 2020 18:47:22
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 18:40:59
User entered 'un UNK 2010'	Heather Leary (b) (4)	05 Aug 2020 18:01:59
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:58:53
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 18:01:59
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:58:55
User entered 'Yes (Y)'	Heather Leary (b) (4)	05 Aug 2020 18:01:59
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:58:52
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 18:01:59
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:58:50
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 18:01:59
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 18:01:59

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 18:01:59

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:46:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 18:01:59

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 19:00:13
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 19:31:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 19:31:46
Data point term sent to Coder Coding entries removed.	System Afifah Ayub (b) (4)	25 Sep 2020 19:30:47 25 Sep 2020 19:30:17
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 18:19:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 18:19:02
Data point term sent to Coder User entered 'Aspirin'	System Heather Leary (b) (4)	05 Aug 2020 18:03:44 05 Aug 2020 18:02:58

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 19:00:12
User entered 'Yes (Y)'	Heather Leary (b) (4)	05 Aug 2020 18:02:58
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 09:14:10
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 19:00:10
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4) (b) (4)	25 Sep 2020 19:30:26
User entered 'Cardiac HEALTH PROPHYLAXIS' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	25 Sep 2020 19:30:17
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 10:40:24
User entered 'Health prophylaxis'	Heather Leary (b) (4) (b) (4)	05 Aug 2020 18:02:58

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 19:00:08
User entered '81'	Heather Leary (b) (4)	05 Aug 2020 18:02:58
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 19:00:07
User entered 'mg (mg)'	Heather Leary (b) (4)	05 Aug 2020 18:02:58
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 19:00:06
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 18:02:58
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 19:00:04
User entered 'once daily (QD)'	Heather Leary (b) (4)	05 Aug 2020 18:02:58
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 19:00:02
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 18:02:58
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:59:58
User entered 'Oral (ORAL)'	Heather Leary (b) (4)	05 Aug 2020 18:02:58
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 19:00:00
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 18:02:58
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:59:55
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 02:41:09
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Subject is currently on the medication.' (Site from System).	Afifah Ayub (b) (4)	05 Aug 2020 18:47:33
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 18:40:59
User entered 'un UNK 2010'	Heather Leary (b) (4)	05 Aug 2020 18:02:58
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:59:52
User entered '0'	Heather Leary (b) (4)	05 Aug 2020 18:02:58
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:59:54
User entered 'Yes (Y)'	Heather Leary (b) (4)	05 Aug 2020 18:02:58
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:59:51
User entered empty.	Heather Leary (b) (4)	05 Aug 2020 18:02:58
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 18:59:49
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 18:02:58
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 18:02:58

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 18:02:58

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:46:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 18:02:58

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:25:40
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	02 Oct 2020 19:00:44
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)	27 Aug 2020 19:22:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:22:59
Data point term sent to Coder	System	27 Aug 2020 14:07:01
User entered 'Influenza Vaccine'	Laura Ngansop Djampou (b) (4)	27 Aug 2020 14:06:24

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:25:40
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:39:05
User closed query 'Per DM CLR: Indication = VACCINATION, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 09:33:57
Query 'Per DM CLR: Indication = VACCINATION, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	18 Dec 2020 14:43:54
DataPoint Un-verified.	(b) (4)	
	Reagan Reed (b) (4)	18 Dec 2020 14:43:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	18 Dec 2020 14:43:45
User opened query 'Per DM CLR: Indication = VACCINATION, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 10:32:19
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 19:00:44
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	27 Aug 2020 14:06:24

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:25:40
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 19:00:44
User entered 'Vaccination'	Laura Ngansop Djampou (b) (4)	27 Aug 2020 14:06:24

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:25:40
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:38:54
User closed query 'Per CDM: Please review "Dose per administration" field and update accordingly else clarify.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 12:05:25
Query 'Per CDM: Please review "Dose per administration" field and update accordingly else clarify.' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	18 Nov 2020 14:10:57
DataPoint Un-verified.	(b) (4)	
	Reagan Reed (b) (4)	18 Nov 2020 14:10:48
User entered '0.5' reason for change: Data Entry Error	Reagan Reed (b) (4)	18 Nov 2020 14:10:48
User opened query 'Per CDM: Please review "Dose per administration" field and update accordingly else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 13:33:59
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 19:00:44
User entered '1 injection'	Laura Ngansop Djampou (b) (4)	27 Aug 2020 14:06:24

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:25:40
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	20 Jan 2021 22:38:56
DataPoint Un-verified.	Reagan Reed (b) (4)	18 Nov 2020 14:10:48
User entered 'mL (mL)' reason for change: Data Entry Error	Reagan Reed (b) (4)	18 Nov 2020 14:10:48
DataPoint Verified.	(b) (4)	02 Oct 2020 19:00:44
User entered 'Other (OTHER)'	Laura Ngansop Djampou (b) (4)	27 Aug 2020 14:06:24

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:25:40
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	20 Jan 2021 22:38:57
DataPoint Un-verified.	Reagan Reed (b) (4)	18 Nov 2020 14:10:48
User entered empty; reason for change Data Entry Error	Reagan Reed (b) (4)	18 Nov 2020 14:10:48
DataPoint Verified.	(b) (4)	02 Oct 2020 19:00:44
User entered '1 injection'	Laura Ngansop Djampou (b) (4)	27 Aug 2020 14:06:24

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:25:40
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 19:00:44
User entered 'once (ONCE)'	Laura Ngansop Djampou (b) (4)	27 Aug 2020 14:06:24

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:25:40
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 19:00:44
User entered empty.	Laura Ngansop Djampou (b) (4)	27 Aug 2020 14:06:24

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:25:40
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 19:00:44
User entered 'Intramuscular (INTRAMUSCULAR)'	Laura Ngansop Djampou (b) (4)	27 Aug 2020 14:06:24

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:30

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:25:40
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 19:00:44
User entered empty.	Laura Ngansop Djampou (b) (4)	27 Aug 2020 14:06:24

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:30

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:25:40
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 19:00:44
User entered '25 Aug 2020'	Laura Ngansop Djampou (b) (4)	27 Aug 2020 14:06:24

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:25:40
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 19:00:44
User entered '0'	Laura Ngansop Djampou (b) (4)	27 Aug 2020 14:06:24

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:25:40
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 19:00:44
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	27 Aug 2020 14:06:24

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:25:40
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 19:00:44
User entered '25 Aug 2020'	Laura Ngansop Djampou (b) (4)	27 Aug 2020 14:06:24

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:25:40
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 19:00:44
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	27 Aug 2020 14:06:24

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:25:40
User entered empty.	System	27 Aug 2020 14:06:24

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:25:40
User entered empty.	System	27 Aug 2020 14:06:24

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:46:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:25:40
User entered empty.	System	27 Aug 2020 14:06:24

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:39:16
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFECTIVES, ATC: FLUOROQUINOLONES, PRODUCT: OFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 22:55:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 22:55:20
Data point term sent to Coder	System	08 Dec 2020 19:50:15
User entered 'Ofloxacin ophthalmic solution'	Afifah Ayub (b) (4)	08 Dec 2020 19:49:28
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:39:20
User entered 'No (N)'	Afifah Ayub (b) (4)	08 Dec 2020 19:49:28
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:39:22
User entered 'bilateral bacterial conjunctivitis'	Afifah Ayub (b) (4)	08 Dec 2020 19:49:28
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:39:25
User entered 'I'	Afifah Ayub (b) (4)	08 Dec 2020 19:49:28
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:39:26
User entered 'Other (OTHER)'	Afifah Ayub (b) (4)	08 Dec 2020 19:49:28
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:30

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:39:30
User entered 'drop'	Afifah Ayub (b) (4)	08 Dec 2020 19:49:28
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:39:32
User entered 'four times daily (QID)'	Afifah Ayub (b) (4)	08 Dec 2020 19:49:28
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:39:33
User entered empty.	Afifah Ayub (b) (4)	08 Dec 2020 19:49:28
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:39:36
User closed query 'Per CDM : Response noted 'this is an eye drop delivered to the eye'. Please review and consider recording Route of admin =Other, specify 'EYE'. Review and amend as appropriate else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 09:59:12
Query 'Per CDM : Response noted 'this is an eye drop delivered to the eye'. Please review and consider recording Route of admin =Other, specify 'EYE'. Review and amend as appropriate else clarify. Thank you.' answered with 'the site will not change the route of administration simply because "eye" is being asked. This is a medical research trial and we will use medical terminology whenever possible. Intraocular is the proper terminology to describe the route and location of an eye drop. Information is correct as entered, no further clarification is needed.' (Site from DM).	Reagan Reed (b) (4)	19 Jan 2021 20:57:33
	(b) (4)	
User opened query 'Per CDM : Response noted 'this is an eye drop delivered to the eye'. Please review and consider recording Route of admin =Other, specify 'EYE'. Review and amend as appropriate else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 18:12:30
Query 'Per CDM : Response noted 'his is an eye drop delivered to the eye'. Please review and consider recording Route of admin =Other, specify 'EYE'. Review and amend as appropriate else clarify. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 18:11:48
User opened query 'Per CDM : Response noted 'his is an eye drop delivered to the eye'. Please review and consider recording Route of admin =Other, specify 'EYE'. Review and amend as appropriate else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 18:11:32
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 18:11:32

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:30

[Route of administration](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'this is an eye drop delivered to the eye. intraocular means in the eye. correct as entered' (Site from DM).	Reagan Reed (b) (4)	19 Jan 2021 14:51:08
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 14:37:31
User entered 'Intraocular (INTRAOCULAR)'	Afifah Ayub (b) (4)	08 Dec 2020 19:49:28

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:30

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:39:40
User entered empty.	Afifah Ayub (b) (4)	08 Dec 2020 19:49:28
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:30

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:39:42
User entered '30 Nov 2020'	Afifah Ayub (b) (4)	08 Dec 2020 19:49:28
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:39:46
User entered '0'	Afifah Ayub (b) (4)	08 Dec 2020 19:49:28
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:39:49
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	08 Dec 2020 19:49:28
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:39:51
User entered empty.	Afifah Ayub (b) (4)	08 Dec 2020 19:49:28
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:39:54
User entered 'No (N)'	Afifah Ayub (b) (4)	08 Dec 2020 19:49:28
	(b) (4)	

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	08 Dec 2020 19:49:28

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 19:49:28

US3212049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:46:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Dec 2020 19:49:28

US3212049

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:46:30

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:27:55
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:58:52
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	31 Mar 2021 18:43:57
User entered 'No (N)'	Afifah Ayub (b) (4)	10 Sep 2020 19:09:38
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:46:30

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:59:17
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered '01 Feb 2021'	Laura Ngansop Djampou (b) (4)	31 Mar 2021 18:44:42

US3212049

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:46:30

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:59:17
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered 'prostate biopsy'	Laura Ngansop Djampou (b) (4)	31 Mar 2021 18:44:42

US3212049

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:46:30

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:59:17
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered 'Other (OTHER)'	Laura Ngansop Djampou (b) (4)	31 Mar 2021 18:44:42

US3212049

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:46:30

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:59:17
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered 'elevated PSA'	Laura Ngansop Djampou (b) (4)	31 Mar 2021 18:44:42

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'USA-US115-2021-MRNA-1273-P301000015'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4)	08 Mar 2021 15:53:58
User entered 'Yes (Y)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4)	08 Mar 2021 15:53:58
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'Yes (Y)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:21:44
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:24
Un-reviewed for Safety.	System	07 Apr 2021 23:28:13
DataPoint Un-verified.	System	07 Apr 2021 23:28:13
Signature has been broken.	System	07 Apr 2021 23:28:13
User entered 'Vicki'	System	07 Apr 2021 23:28:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4)	09 Mar 2021 14:45:36
Un-reviewed for Safety.	System	08 Mar 2021 15:54:26
User entered empty.	System	08 Mar 2021 15:54:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'Vicki'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:21:45
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:24
Un-reviewed for Safety.	System	07 Apr 2021 23:28:13
DataPoint Un-verified.	System	07 Apr 2021 23:28:13
Signature has been broken.	System	07 Apr 2021 23:28:13
User entered 'Miller'	System	07 Apr 2021 23:28:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4)	09 Mar 2021 14:45:36
Un-reviewed for Safety.	System	08 Mar 2021 15:54:26
User entered empty.	System	08 Mar 2021 15:54:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'Miller'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'US'	System	25 Feb 2021 16:48:20

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	20 Apr 2021 17:25:53
User entered '4'	System	07 Apr 2021 23:28:13
User entered '3'	System	09 Mar 2021 14:45:50
User entered '2'	System	08 Mar 2021 15:54:26
User entered '1'	System	25 Feb 2021 16:48:20

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'USA-US115-2021-MRNA-1273-P301000015'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4)	08 Mar 2021 15:53:58
User entered 'Yes (Y)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4)	08 Mar 2021 15:53:58
User entered 'Yes (Y)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:21:44
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:24
Un-reviewed for Safety.	System	07 Apr 2021 23:28:13
DataPoint Un-verified.	System	07 Apr 2021 23:28:13
Signature has been broken.	System	07 Apr 2021 23:28:13
User entered 'Vicki'	System	07 Apr 2021 23:28:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4)	09 Mar 2021 14:45:36
Un-reviewed for Safety.	System	08 Mar 2021 15:54:26
User entered empty.	System	08 Mar 2021 15:54:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'Vicki'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:21:45
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:24
Un-reviewed for Safety.	System	07 Apr 2021 23:28:13
DataPoint Un-verified.	System	07 Apr 2021 23:28:13
Signature has been broken.	System	07 Apr 2021 23:28:13
User entered 'Miller'	System	07 Apr 2021 23:28:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4)	09 Mar 2021 14:45:36
Un-reviewed for Safety.	System	08 Mar 2021 15:54:26
User entered empty.	System	08 Mar 2021 15:54:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'Miller'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'US'	System	25 Feb 2021 16:48:20

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	20 Apr 2021 17:25:53
User entered '4'	System	07 Apr 2021 23:28:13
User entered '3'	System	09 Mar 2021 14:45:50
User entered '2'	System	08 Mar 2021 15:54:26
User entered '1'	System	25 Feb 2021 16:48:20

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:46:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered '25/Feb/2021 10:48'	(b) (4) System	25 Feb 2021 16:48:20

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:46:30

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered '1'	(b) (4), (b) (6)	25 Feb 2021 16:48:20

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'USA-US115-2021-MRNA-1273-P301000015'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4)	08 Mar 2021 15:53:58
User entered 'Yes (Y)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4)	08 Mar 2021 15:53:58
User entered 'Yes (Y)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:21:44
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:24
Un-reviewed for Safety.	System	07 Apr 2021 23:28:13
DataPoint Un-verified.	System	07 Apr 2021 23:28:13
Signature has been broken.	System	07 Apr 2021 23:28:13
User entered 'Vicki'	System	07 Apr 2021 23:28:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4)	09 Mar 2021 14:45:36
Un-reviewed for Safety.	System	08 Mar 2021 15:54:26
User entered empty.	System	08 Mar 2021 15:54:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'Vicki'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:21:45
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:24
Un-reviewed for Safety.	System	07 Apr 2021 23:28:13
DataPoint Un-verified.	System	07 Apr 2021 23:28:13
Signature has been broken.	System	07 Apr 2021 23:28:13
User entered 'Miller'	System	07 Apr 2021 23:28:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 14:45:36
Un-reviewed for Safety.	System	08 Mar 2021 15:54:26
User entered empty.	System	08 Mar 2021 15:54:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'Miller'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'US'	System	25 Feb 2021 16:48:20

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	20 Apr 2021 17:25:53
User entered '4'	System	07 Apr 2021 23:28:13
User entered '3'	System	09 Mar 2021 14:45:50
User entered '2'	System	08 Mar 2021 15:54:26
User entered '1'	System	25 Feb 2021 16:48:20

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:46:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered '08/Mar/2021 09:54'	(b) (4) System	08 Mar 2021 15:54:26

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:46:30

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:45:36
User entered 'I'	(b) (4), (b) (6)	08 Mar 2021 15:54:26

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'USA-US115-2021-MRNA-1273-P301000015'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4)	08 Mar 2021 15:53:58
User entered 'Yes (Y)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'Yes (Y)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:21:44
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:24
Un-reviewed for Safety.	System	07 Apr 2021 23:28:13
DataPoint Un-verified.	System	07 Apr 2021 23:28:13
Signature has been broken.	System	07 Apr 2021 23:28:13
User entered 'Vicki'	System	07 Apr 2021 23:28:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4)	09 Mar 2021 14:45:36
Un-reviewed for Safety.	System	08 Mar 2021 15:54:26
User entered empty.	System	08 Mar 2021 15:54:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'Vicki'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:21:45
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:24
Un-reviewed for Safety.	System	07 Apr 2021 23:28:13
DataPoint Un-verified.	System	07 Apr 2021 23:28:13
Signature has been broken.	System	07 Apr 2021 23:28:13
User entered 'Miller'	System	07 Apr 2021 23:28:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 14:45:36
Un-reviewed for Safety.	System	08 Mar 2021 15:54:26
User entered empty.	System	08 Mar 2021 15:54:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'Miller'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'US'	System	25 Feb 2021 16:48:20

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	20 Apr 2021 17:25:53
User entered '4'	System	07 Apr 2021 23:28:13
User entered '3'	System	09 Mar 2021 14:45:50
User entered '2'	System	08 Mar 2021 15:54:26
User entered '1'	System	25 Feb 2021 16:48:20

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:46:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered '09/Mar/2021 14:45'	(b) (4) System	09 Mar 2021 14:45:50

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:46:30

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)	07 Apr 2021 23:28:03
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
User entered 'I'	(b) (4), (b) (6)	09 Mar 2021 14:45:50

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'USA-US115-2021-MRNA-1273-P301000015'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'Yes (Y)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'Yes (Y)'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:21:44
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:24
Un-reviewed for Safety.	System	07 Apr 2021 23:28:13
DataPoint Un-verified.	System	07 Apr 2021 23:28:13
Signature has been broken.	System	07 Apr 2021 23:28:13
User entered 'Vicki'	System	07 Apr 2021 23:28:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4)	09 Mar 2021 14:45:36
Un-reviewed for Safety.	System	08 Mar 2021 15:54:26
User entered empty.	System	08 Mar 2021 15:54:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'Vicki'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:21:45
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:24
Un-reviewed for Safety.	System	07 Apr 2021 23:28:13
DataPoint Un-verified.	System	07 Apr 2021 23:28:13
Signature has been broken.	System	07 Apr 2021 23:28:13
User entered 'Miller'	System	07 Apr 2021 23:28:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 14:45:36
Un-reviewed for Safety.	System	08 Mar 2021 15:54:26
User entered empty.	System	08 Mar 2021 15:54:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'Miller'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

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Generated On: 09 Jun 2021 15:46:30

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4)	08 Mar 2021 15:53:58
User entered 'US'	System	25 Feb 2021 16:48:20

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	20 Apr 2021 17:25:53
User entered '4'	System	07 Apr 2021 23:28:13
User entered '3'	System	09 Mar 2021 14:45:50
User entered '2'	System	08 Mar 2021 15:54:26
User entered '1'	System	25 Feb 2021 16:48:20

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:46:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:27:12
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:24
User entered '07/Apr/2021 19:28'	System	07 Apr 2021 23:28:13

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:46:30

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:27:12
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:24
User entered 'I'	(b) (4), (b) (6)	07 Apr 2021 23:28:13

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'USA-US115-2021-MRNA-1273-P301000015'	System	25 Feb 2021 16:48:03

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Folder: SAE USA-US115-2021-MRNA-1273-P301000015

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Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'Yes (Y)'	System	25 Feb 2021 16:48:03

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Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

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Form: Safety Report Form

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

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Form: Safety Report Form

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

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Form: Safety Report Form

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'No (N)'	System	25 Feb 2021 16:48:03

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Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'Yes (Y)'	System	25 Feb 2021 16:48:03

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Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:21:44
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:24
Un-reviewed for Safety.	System	07 Apr 2021 23:28:13
DataPoint Un-verified.	System	07 Apr 2021 23:28:13
Signature has been broken.	System	07 Apr 2021 23:28:13
User entered 'Vicki'	System	07 Apr 2021 23:28:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4)	09 Mar 2021 14:45:36
Un-reviewed for Safety.	System	08 Mar 2021 15:54:26
User entered empty.	System	08 Mar 2021 15:54:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'Vicki'	System	25 Feb 2021 16:48:03

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Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:21:45
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:24
Un-reviewed for Safety.	System	07 Apr 2021 23:28:13
DataPoint Un-verified.	System	07 Apr 2021 23:28:13
Signature has been broken.	System	07 Apr 2021 23:28:13
User entered 'Miller'	System	07 Apr 2021 23:28:13
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4)	09 Mar 2021 14:45:36
Un-reviewed for Safety.	System	08 Mar 2021 15:54:26
User entered empty.	System	08 Mar 2021 15:54:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'Miller'	System	25 Feb 2021 16:48:03

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 21:44:56
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:00:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:53:58
User entered 'US'	System	25 Feb 2021 16:48:20

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:46:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	20 Apr 2021 17:25:53
User entered '4'	System	07 Apr 2021 23:28:13
User entered '3'	System	09 Mar 2021 14:45:50
User entered '2'	System	08 Mar 2021 15:54:26
User entered '1'	System	25 Feb 2021 16:48:20

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:46:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:55:11
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:24
User entered '20/Apr/2021 10:25'	(b) (4) System	20 Apr 2021 17:25:53

US3212049

Folder: SAE USA-US115-2021-MRNA-1273-P301000015

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:46:30

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:55:11
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:24
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:25:53