

US3212028 (Prod: DM Clinical Research - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:45:33

All time stamps listed in this document are displayed in GMT

US3212028

Form: Participant Creation

Data signed: (b) (4) 29 Mar 2021 19:12:25

Generated On: 09 Jun 2021 15:45:33

Participant ID

US3212028

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

US3212028

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

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

Visit date (dd MMM yyyy)	04 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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US3212028

Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	67
Age Units	YEARS
Age (Derived)	67
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

US3212028

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Date of Informed Consent (*dd MMM yyyy*) 04 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

US3212028

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3212028

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Mar 2021 17:51:09

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Condition	BILATERAL TOTAL HIP REPLACEMENT
Start date (dd MMM yyyy)	10 APR 2018
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)	10 APR 2018
Stop date completely unknown	False
Start Month and Year (derived)	APR 2018
Start Year (derived)	2018
Stop Month and Year (derived)	APR 2018
Stop Year (derived)	2018

US3212028

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

US3212028

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

US3212028

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3212028

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Condition	NEPHROLITHIASIS (LEFT)
Start date (dd MMM yyyy)	UN OCT 2017
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 OCT 2017
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2017
Start Year (derived)	2017
Stop Month and Year (derived)	OCT 2017
Stop Year (derived)	2017

US3212028

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Condition	GENETIC BILATERAL HIP DYSPLASIA
Start date (dd MMM yyyy)	(b) (6) 1953
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)	10 APR 2018
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1953
Start Year (derived)	1953
Stop Month and Year (derived)	APR 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	04 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:48 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 11:48
Height (<i>xxx.x</i>)	68 in
Weight (<i>xxx.x</i>)	172 lb
BMI (<i>xxx.x</i>)	26.20719 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 17:51:09

Generated On: 09 Jun 2021 15:45:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Mar 2021 17:51:09

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify RETIRED

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 17:51:09

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	PARTICIPANT ATTENDED LARGE GROUP EVENTS IN THE PAST FEW WEEKS (E.G., WEDDING, PLACES OF WORSHIP, CONCERT). COHABITATION/LIVING IN THE SAME HOUSEHOLD AS SOMEONE WORKING AT A HIGH OCCUPATIONAL RISK JOB.

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

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

Visit date (dd MMM yyyy)	04 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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US3212028

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

What was the date of randomization? (dd MMM yyyy) 04 AUG 2020

What was the participant's randomization number? 184484

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

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)	04 AUG 2020
Time of assessment (00:00-23:59)	11:48 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 11:48
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 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 17:51:09

Generated On: 09 Jun 2021 15:45:33

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 AUG 2020
Time of assessment (00:00-23:59)	13:50 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 13:50
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)	56 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

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

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.

US3212028

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

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) 04 AUG 2020

What was the treatment time? (00:00-23:59) 13:06 (24 HR)

Treatment Date and Time (derived) 04 AUG 2020 13:06

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 04 AUG 2020

Collection time (00:00-23:59) 12:27 (24 HR)

Collection date and time (derived) 04 AUG 2020 12:27

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Collection date (dd MMM yyyy)			04 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:21	04 AUG 2020 12:21
Nasopharyngeal Swab 2	No		

US3212028

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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

97.7 °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

04 AUG 2020 13:42

PC Open Date & Time

04 AUG 2020 13:26

PC Close Date & Time

04 AUG 2020 15:56

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

PC Time Stamp	04 AUG 2020 19:57
PC Open Date & Time	04 AUG 2020 16:51
PC Close Date & Time	05 AUG 2020 11:59

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 18:03

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

06 AUG 2020 15:46

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 18:09

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

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

08 AUG 2020 16:34

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

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

97.6 °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 AUG 2020 16:53

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 18:07

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 13:43

PC Open Date & Time

04 AUG 2020 13:26

PC Close Date & Time

04 AUG 2020 15:56

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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

04 AUG 2020 19:58

PC Open Date & Time

04 AUG 2020 16:51

PC Close Date & Time

05 AUG 2020 11:59

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

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

05 AUG 2020 18:03

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

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

06 AUG 2020 15:46

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

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

07 AUG 2020 18:09

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

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

08 AUG 2020 16:34

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

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

09 AUG 2020 16:53

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

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

10 AUG 2020 18:08

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 13:44
PC Open Date & Time	04 AUG 2020 13:26
PC Close Date & Time	04 AUG 2020 15:56

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 19:59
PC Open Date & Time	04 AUG 2020 16:51
PC Close Date & Time	05 AUG 2020 11:59

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

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 ☒

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 18:04
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

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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49 of 2216

EAB) (1725)

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 15:46
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

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 ☒

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 18:09
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

53 of 2216

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 16:34
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

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 ☒

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 16:54
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

57 of 2216

EAB) (1725)

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 18:08
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3212028

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3212028

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212028

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3212028

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212028

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3212028

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212028

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

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

Visit date (dd MMM yyyy)	01 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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US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

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)	01 SEP 2020
Time of assessment (00:00-23:59)	11:48 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 11:48
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)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

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)	01 SEP 2020
Time of assessment (00:00-23:59)	13:09 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 13:09
Temperature (xxx.x)	96.9 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3212028

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 SEP 2020

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

US3212028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

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) 01 SEP 2020

What was the treatment time? (00:00-23:59) 12:37 (24 HR)

Treatment Date and Time (derived) 01 SEP 2020 12:37

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

US3212028

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 01 SEP 2020

Collection time (00:00-23:59) 12:22 (24 HR)

Collection date and time (derived) 01 SEP 2020 12:22

US3212028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Collection date (dd MMM yyyy)			01 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:18	01 SEP 2020 12:18
Nasopharyngeal Swab 2	No		

US3212028

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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 96.9 °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 01 SEP 2020 13:11

PC Open Date & Time 01 SEP 2020 12:57

PC Close Date & Time 01 SEP 2020 15:27

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °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	01 SEP 2020 16:45
PC Open Date & Time	01 SEP 2020 16:22
PC Close Date & Time	02 SEP 2020 11:59

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

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 100.4 °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):

To **TREAT** pain or fever that has already occurred True

To **PREVENT** pain or fever from occurring False

PC Time Stamp 02 SEP 2020 13:10

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °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

03 SEP 2020 12:58

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

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

04 SEP 2020 13:57

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 14:08

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

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

06 SEP 2020 15:24

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

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

97.6 °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

07 SEP 2020 13:38

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 13:12

PC Open Date & Time

01 SEP 2020 12:57

PC Close Date & Time

01 SEP 2020 15:27

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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

01 SEP 2020 16:45

PC Open Date & Time

01 SEP 2020 16:22

PC Close Date & Time

02 SEP 2020 11:59

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

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

02 SEP 2020 13:11

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

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

03 SEP 2020 12:58

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

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

04 SEP 2020 13:57

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

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

05 SEP 2020 14:08

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

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

06 SEP 2020 15:24

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

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

07 SEP 2020 13:38

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 13:12
---------------	-------------------

PC Open Date & Time	01 SEP 2020 12:57
---------------------	-------------------

PC Close Date & Time	01 SEP 2020 15:27
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US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 16:45
PC Open Date & Time	01 SEP 2020 16:22
PC Close Date & Time	02 SEP 2020 11:59

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

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)

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 13:12
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

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 ☒

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

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

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

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 ☒

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 13:58
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 14:09
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

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

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EAB) (1725)

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 15:24
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

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 ☒

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 13:38
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3212028

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3212028

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212028

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3212028

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212028

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3212028

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212028

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

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

Visit date (dd MMM yyyy)	28 SEP 2020
--------------------------	-------------

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

Folder OID	VISIT3
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US3212028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	28 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:19 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 10:19
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212028

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3212028

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

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

Collection date (dd MMM yyyy)	28 SEP 2020
-------------------------------	-------------

Collection time (00:00-23:59)	10:44 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	28 SEP 2020 10:44
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US3212028

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

04 OCT 2020 14:23:55

Patient Cloud Open Date & Time

04 OCT 2020 00:01

Patient Cloud Close Date & Time

08 OCT 2020 23:59

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

11 OCT 2020 16:25:25

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 OCT 2020 13:18:22

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	03 NOV 2020 06:15:13
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 NOV 2020 16:03:58

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

15 NOV 2020 18:01:43

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 <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 NOV 2020 17:02:15
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

26 NOV 2020 18:01:54

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 10:31:12

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

10 DEC 2020 09:07:00

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

17 DEC 2020 20:34:47

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

24 DEC 2020 17:44:21

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

02 JAN 2021 18:19:04

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 10:15:49

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 16:47:44

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

23 JAN 2021 15:59:41

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 09:45:14

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 13:48:48

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

22 FEB 2021 09:57:40

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

01 MAR 2021 09:17:50

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 13:07:50

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

13 MAR 2021 07:16:58

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

19 MAR 2021 19:24:50

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

27 MAR 2021 17:26:57

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 16:31:59

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

08 APR 2021 12:44:45

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

15 APR 2021 12:05:14

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

22 APR 2021 17:54:41

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

01 MAY 2021 09:59:42

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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°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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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°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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 <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"/>

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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"/>

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2021 00:01
Patient Cloud Close Date & Time	28 JUN 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°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"/>

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2021 00:01
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Patient Cloud Close Date & Time	16 AUG 2021 23:59
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US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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="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"/>

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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"/>

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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°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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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°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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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°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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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"/>

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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°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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 544

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 FEB 2022 00:01
Patient Cloud Close Date & Time	14 FEB 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 614

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

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

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

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

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

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

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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°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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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"/>

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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="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"/>

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2022 00:01
Patient Cloud Close Date & Time	20 JUN 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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="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"/>

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 719

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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"/>

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 AUG 2022 00:01
Patient Cloud Close Date & Time	29 AUG 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 SEP 2022 00:01
Patient Cloud Close Date & Time	03 OCT 2022 23:59

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3212028

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:45:33

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 09:18:03

US3212028

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments ATTEMPTED DAY 85 SAFETY
CALL. NO ANSWER

If Contact Not Made, please provide Comments

US3212028

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:51:09

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212028

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 19:17:58

Generated On: 09 Jun 2021 15:45:33

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 02 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3212028

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 19:17:58

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212028

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 19:17:58

Generated On: 09 Jun 2021 15:45:33

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3212028

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 19:17:58

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212028

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 19:17:58

Generated On: 09 Jun 2021 15:45:33

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3212028

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 19:17:58

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212028

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 19:17:58

Generated On: 09 Jun 2021 15:45:33

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

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

Folder OID	VISIT4
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US3212028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 19:17:59

Generated On: 09 Jun 2021 15:45:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	12:11 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 12:11
Temperature (<i>xxx.x</i>)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	62 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212028

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 19:17:58

Generated On: 09 Jun 2021 15:45:33

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.

US3212028

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 19:17:58

Generated On: 09 Jun 2021 15:45:33

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

Collection date (dd MMM yyyy)	24 FEB 2021
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Collection time (00:00-23:59)	12:40 (24 HR)
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Collection date and time (derived)	24 FEB 2021 12:40
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US3212028

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 19:17:58

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212028

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 19:17:58

Generated On: 09 Jun 2021 15:45:33

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3212028

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 19:17:58

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212028

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 30 Apr 2021 18:12:49

Generated On: 09 Jun 2021 15:45:33

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3212028

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 30 Apr 2021 18:12:49

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212028

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

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

US3212028

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3212028

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:45:33

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"/>

US3212028

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:45:33

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3212028

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

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 19:17:57

Generated On: 09 Jun 2021 15:45:33

Was this visit performed? Yes ☒
No ☐

Visit date (dd MMM yyyy) 15 JAN 2021

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

Folder OID UNBLND_DECIDE

US3212028

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 19:23:55

Generated On: 09 Jun 2021 15:45:33

Date of updated informed consent (dd MMM yyyy) 15 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) 15 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 _____

US3212028

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 19:17:57

Generated On: 09 Jun 2021 15:45:33

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 15 JAN 2021

Collection time (00:00-23:59) 10:50 (24 HR)

Collection date and time (derived) 15 JAN 2021 10:50

US3212028

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 29 Mar 2021 19:12:28

Generated On: 09 Jun 2021 15:45:33

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

Collection date (dd MMM yyyy)	15 JAN 2021
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Collection time (00:00 - 23:59)	10:48
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Collection Date and Time (derived)	15 JAN 2021 10:48
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US3212028

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 29 Mar 2021 19:12:27

Generated On: 09 Jun 2021 15:45:33

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Mar 2021 19:12:25

Generated On: 09 Jun 2021 15:45:33

AEID	USA-US115-2020-MRNA-1273-P30 1000007
Adverse event	ACUTE CORONARY SYNDROME (NON ST ELEVATED MYOCARDIAL INFARCTION)
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)	20 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	23 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	29 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/>

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	Unknown	<input type="radio"/>
<hr/>		
Number of Days in ICU		
Persistent or significant disability or incapacity		False
Congenital anomaly or birth defect		False
Other medically important event		False
Relationship to investigational product	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
Relationship to Study Procedure	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
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"/>
<hr/>		
Other action taken (check all that apply)		
None		False
Concomitant Medication		True
Concomitant Procedure		True
Outcome	Fatal	<input type="radio"/>
	Not Recovered/Not Resolved	<input type="radio"/>
	Recovered/Resolved	<input checked="" type="radio"/>
	Recovered/Resolved with Sequelae	<input type="radio"/>
	Recovering/Resolving	<input type="radio"/>
	Unknown	<input type="radio"/>
<hr/>		
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:		
Narrative	CORONARY ARTERY DISEASE REQUIRING CORONARY ARTERY BYPASS GRAFT X 2 VESSELS. SUBJECT TESTED NEGATIVE FOR COVID19 IN HOSPITAL ON 20OCT2020.	

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

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Folder: Adverse Events

Form: Adverse Events (2)

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AEID	
Adverse event	GASTROESOPHAGEAL REFLUX DISEASE
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)	28 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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 (3)

Data signed: (b) (4) 29 Mar 2021 19:12:25

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AEID	
Adverse event	WORSENING OF HYPERTENSION
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)	29 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Form: Adverse Events (3)

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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 (4)

Data signed: (b) (4) 29 Mar 2021 19:12:25

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AEID	
Adverse event	WORSENING OF HYPERCHOLESTEROLEMIA
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)	29 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input 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 (5)

Data signed: (b) (4) 29 Mar 2021 19:12:25

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AEID

Adverse event

POST OPERATIVE PAIN

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)

23 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 NOV 2020

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

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Folder: Adverse Events

Form: Adverse Events (5)

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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 checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 29 Mar 2021 19:12:28

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Mar 2021 19:12:27

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Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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	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 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	29 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Mar 2021 19:12:27

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Name of Medication TRIAMTERENE HCTZ

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 37.5-25

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 (2)

Data signed: (b) (4) 29 Mar 2021 19:12:27

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	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 2000
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) 29 Mar 2021 19:12:27

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Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Mar 2021 19:12:27

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	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 2017	
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) 29 Mar 2021 19:12:27

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Name of Medication ADVIL (IBUPROFEN)

Prophylaxis Yes ☐
No ☒

Indication FEVER/PAIN REACTOGENICITY

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Mar 2021 19:12:27

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	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)		02 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Mar 2021 19:12:27

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Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication IMMUNIZATION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Mar 2021 19:12:27

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	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)		16 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		16 SEP 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 (6)

Data signed: (b) (4) 29 Mar 2021 19:12:27

Generated On: 09 Jun 2021 15:45:33

Name of Medication PANTOPRAZOLE SODIUM DR

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 40

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) 29 Mar 2021 19:12:27

Generated On: 09 Jun 2021 15:45:33

	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)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Mar 2021 19:12:27

Generated On: 09 Jun 2021 15:45:33

Name of Medication AMIODARONE

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 200

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) 29 Mar 2021 19:12:27

Generated On: 09 Jun 2021 15:45:33

	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)	29 OCT 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)	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 (8)

Data signed: (b) (4) 29 Mar 2021 19:12:27

Generated On: 09 Jun 2021 15:45:33

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE PAIN,
CORONARY ARTERY BYPASS
GRAFT

Dose per administration 100

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 (8)

Data signed: (b) (4) 29 Mar 2021 19:12:27

Generated On: 09 Jun 2021 15:45:33

	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)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Mar 2021 19:12:27

Generated On: 09 Jun 2021 15:45:33

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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 (9)

Data signed: (b) (4) 29 Mar 2021 19:12:27

Generated On: 09 Jun 2021 15:45:33

	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)	29 OCT 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)	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 (10)

Data signed: (b) (4) 29 Mar 2021 19:12:27

Generated On: 09 Jun 2021 15:45:33

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 80

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 (10)

Data signed: (b) (4) 29 Mar 2021 19:12:27

Generated On: 09 Jun 2021 15:45:33

	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)	29 OCT 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)	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 (11)

Data signed: (b) (4) 29 Mar 2021 19:12:27

Generated On: 09 Jun 2021 15:45:33

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC 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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Mar 2021 19:12:27

Generated On: 09 Jun 2021 15:45:33

	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)	UN UNK 2005	
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 (12)

Data signed: (b) (4) 29 Mar 2021 19:12:27

Generated On: 09 Jun 2021 15:45:33

Name of Medication CENTRUM COMPLETE
MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication ILLNESS PROPHYLAXIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Mar 2021 19:12:27

Generated On: 09 Jun 2021 15:45:33

	Intraocular	<input 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)	UN UNK 2000	
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 (13)

Data signed: (b) (4) 29 Mar 2021 19:12:27

Generated On: 09 Jun 2021 15:45:33

Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication VITAMIN D DEFICIENCY
PROPHYLAXIS

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Mar 2021 19:12:27

Generated On: 09 Jun 2021 15:45:33

	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 2000	
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 (14)

Data signed: (b) (4) 29 Mar 2021 19:12:27

Generated On: 09 Jun 2021 15:45:33

Name of Medication FOLIC ACID

Prophylaxis Yes ☒
No ☐

Indication FOLIC ACID DEFICIENCY
PROPHYLAXIS

Dose per administration 800

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 (14)

Data signed: (b) (4) 29 Mar 2021 19:12:27

Generated On: 09 Jun 2021 15:45:33

	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 2000	
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 (15)

Data signed: (b) (4) 29 Mar 2021 19:12:27

Generated On: 09 Jun 2021 15:45:33

Name of Medication GLUCOSAMINE-CHONDROITIN

Prophylaxis Yes ☒
No ☐

Indication JOINT; GENERAL HEALTH

Dose per administration 500-400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Mar 2021 19:12:27

Generated On: 09 Jun 2021 15:45:33

	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)	UN UNK 2000	
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 (16)

Data signed: (b) (4) 29 Mar 2021 19:12:27

Generated On: 09 Jun 2021 15:45:33

Name of Medication TRIAMTERENE-HYDROCHLORO
THIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 37.5-25

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 (16)

Data signed: (b) (4) 29 Mar 2021 19:12:27

Generated On: 09 Jun 2021 15:45:33

	Intraocular	<input 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)	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"/>

US3212028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 29 Mar 2021 19:12:28

Generated On: 09 Jun 2021 15:45:33

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3212028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 29 Mar 2021 19:12:28

Generated On: 09 Jun 2021 15:45:33

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
23 OCT 2020	CORONARY ARTERY BYPASS GRAFT	Adverse Event	

US3212028

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:45:33

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

US3212028

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 01 Apr 2021 19:17:57

Generated On: 09 Jun 2021 15:45:33

SAEID	USA-US115-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 01 Apr 2021 19:17:57

Generated On: 09 Jun 2021 15:45:33

SAEID	USA-US115-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	29/OCT/2020 13:24
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

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 01 Apr 2021 19:17:57

Generated On: 09 Jun 2021 15:45:33

SAEID	USA-US115-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	09/NOV/2020 14:43
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

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 01 Apr 2021 19:17:57

Generated On: 09 Jun 2021 15:45:33

SAEID	USA-US115-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	19/NOV/2020 11:40
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

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 01 Apr 2021 19:17:57

Generated On: 09 Jun 2021 15:45:33

SAEID	USA-US115-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	24/NOV/2020 19:45
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

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Data signed: (b) (4) 01 Apr 2021 19:17:57

Generated On: 09 Jun 2021 15:45:33

SAEID	USA-US115-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	06/DEC/2020 16:24
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

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Data signed: (b) (4) 01 Apr 2021 19:17:57

Generated On: 09 Jun 2021 15:45:33

SAEID	USA-US115-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	10/DEC/2020 14:31
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3212028 (Prod: DM Clinical Research - ERN - PPDS)

US3212028

Form: Participant Creation

Generated On: 09 Jun 2021 15:45:33

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered 'US3212028'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 17:19:18

US3212028

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Aug 2020 17:26:13

US3212028

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '04 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 17:19:19

US3212028

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

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 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4)	04 Aug 2020 17:26:13

US3212028

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered 'SCRN'	System	04 Aug 2020 17:26:13

US3212028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered (b) (6) 1953'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 17:19:20

US3212028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '67'	Afifah Ayub (b) (4)	04 Aug 2020 17:26:32

US3212028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered 'YEARS'	System	04 Aug 2020 17:26:32

US3212028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered '67'	System	04 Aug 2020 17:26:49

US3212028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Male (M)'	Afifah Ayub (b) (4)	04 Aug 2020 17:26:32

US3212028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Afifah Ayub (b) (4)	04 Aug 2020 17:26:32

US3212028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'I'	Afifah Ayub (b) (4)	04 Aug 2020 17:26:32

US3212028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '0'	Afifah Ayub (b) (4)	04 Aug 2020 17:26:32

US3212028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '0'	Afifah Ayub (b) (4)	04 Aug 2020 17:26:32

US3212028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '0'	Afifah Ayub (b) (4)	04 Aug 2020 17:26:32

US3212028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '0'	Afifah Ayub (b) (4)	04 Aug 2020 17:26:32

US3212028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '0'	Afifah Ayub (b) (4)	04 Aug 2020 17:26:32

US3212028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty.	Afifah Ayub (b) (4)	04 Aug 2020 17:26:32

US3212028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '0'	Afifah Ayub (b) (4)	04 Aug 2020 17:26:32

US3212028

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '0'	Afifah Ayub (b) (4)	04 Aug 2020 17:26:32

US3212028

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:33

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '04 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	03 Dec 2020 18:38:23
User entered '4 Aug 2020'	Afifah Ayub (b) (4)	04 Aug 2020 17:26:49

7

US3212028

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered 'Aug 2020'	System	04 Aug 2020 17:26:49

US3212028

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered '2020'	System	04 Aug 2020 17:26:49

US3212028

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:33

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Amendment 1 (1)'	Afifah Ayub (b) (4)	04 Aug 2020 17:26:49

US3212028

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Aug 2020 17:26:49

US3212028

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty.	Afifah Ayub (b) (4)	04 Aug 2020 17:26:49

US3212028

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:33

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty.	Afifah Ayub (b) (4)	04 Aug 2020 17:26:49

US3212028

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:33

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Aug 2020 17:26:49

US3212028

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:33

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 17:19:19

US3212028

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:33

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered 'I'	System	04 Aug 2020 17:26:54

US3212028

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Aug 2020 17:26:54

US3212028

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:45:33

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Aug 2020 17:27:12

US3212028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:45:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 12:26:58
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Total hip replacement - version MedDRA\23.0.	Coder Import (b) (4)	13 Oct 2020 19:16:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Oct 2020 19:16:26
Data point term sent to Coder	System	13 Oct 2020 19:15:23
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'Verified and updated' (Site from DM).	Nirja Shah (b) (4)	13 Oct 2020 19:14:43
Coding entries removed.	Nirja Shah (b) (4)	13 Oct 2020 19:14:25
User entered 'BILATERAL TOTAL HIP REPLACEMENT' reason for change: Data Entry Error	Nirja Shah (b) (4)	13 Oct 2020 19:14:25
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 13:39:11
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Total hip replacement - version MedDRA\23.0.	Coder Import (b) (4)	04 Aug 2020 17:28:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Aug 2020 17:28:59
Data point term sent to Coder	System	04 Aug 2020 17:27:55

US3212028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:45:33

[Condition](#)

Audit	User	Time (GMT)
User entered 'Total Hip Replacement'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:27:38

US3212028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '10 Apr 2018'	Afifah Ayub (b) (4)	04 Aug 2020 17:27:38

US3212028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '0'	Afifah Ayub (b) (4)	04 Aug 2020 17:27:38

US3212028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:45:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Aug 2020 17:27:38

US3212028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '10 Apr 2018'	Afifah Ayub (b) (4)	04 Aug 2020 17:27:38

US3212028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:45:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '0'	Afifah Ayub (b) (4)	04 Aug 2020 17:27:38

US3212028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered 'Apr 2018'	System	04 Aug 2020 17:27:38

US3212028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered '2018'	System	04 Aug 2020 17:27:38

US3212028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered 'Apr 2018'	System	04 Aug 2020 17:27:38

US3212028

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered '2018'	System	04 Aug 2020 17:27:38

US3212028

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
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)	04 Aug 2020 17:30:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 17:30:10
Data point term sent to Coder	System	04 Aug 2020 17:28:58
User entered 'Hypertension'	Afifah Ayub (b) (4)	04 Aug 2020 17:27:59

US3212028

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'UN UNK 2000'	Afifah Ayub (b) (4)	04 Aug 2020 17:27:59

US3212028

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '0'	Afifah Ayub (b) (4)	04 Aug 2020 17:27:59

US3212028

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Aug 2020 17:27:59

US3212028

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty.	Afifah Ayub (b) (4)	04 Aug 2020 17:27:59

US3212028

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '0'	Afifah Ayub (b) (4)	04 Aug 2020 17:27:59

US3212028

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered 'Jan 2000'	System	04 Aug 2020 17:27:59

US3212028

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered '2000'	System	04 Aug 2020 17:27:59

US3212028

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered empty.	System	04 Aug 2020 17:27:59

US3212028

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered empty.	System	04 Aug 2020 17:27:59

US3212028

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
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)	04 Aug 2020 17:30:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 17:30:09
Data point term sent to Coder	System	04 Aug 2020 17:28:58
User entered 'Hypercholesterolemia'	Afifah Ayub (b) (4)	04 Aug 2020 17:28:17

US3212028

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'UN UNK 2000'	Afifah Ayub (b) (4)	04 Aug 2020 17:28:17

US3212028

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '0'	Afifah Ayub (b) (4)	04 Aug 2020 17:28:17

US3212028

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Aug 2020 17:28:17

US3212028

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty.	Afifah Ayub (b) (4)	04 Aug 2020 17:28:17

US3212028

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '0'	Afifah Ayub (b) (4)	04 Aug 2020 17:28:17

US3212028

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered 'Jan 2000'	System	04 Aug 2020 17:28:17

US3212028

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered '2000'	System	04 Aug 2020 17:28:17

US3212028

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered empty.	System	04 Aug 2020 17:28:17

US3212028

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered empty.	System	04 Aug 2020 17:28:17

US3212028

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 17:30:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 17:30:09
Data point term sent to Coder	System	04 Aug 2020 17:28:58
User entered 'Hypothyroidism'	Afifah Ayub (b) (4)	04 Aug 2020 17:28:36

US3212028

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'UN UNK 2017'	Afifah Ayub (b) (4)	04 Aug 2020 17:28:36

US3212028

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '0'	Afifah Ayub (b) (4)	04 Aug 2020 17:28:36

US3212028

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Aug 2020 17:28:36

US3212028

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty.	Afifah Ayub (b) (4)	04 Aug 2020 17:28:36

US3212028

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '0'	Afifah Ayub (b) (4)	04 Aug 2020 17:28:36

US3212028

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered 'Jan 2017'	System	04 Aug 2020 17:28:36

US3212028

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered '2017'	System	04 Aug 2020 17:28:36

US3212028

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered empty.	System	04 Aug 2020 17:28:36

US3212028

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered empty.	System	04 Aug 2020 17:28:36

US3212028

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User closed query 'Per DM CLR: Please specify laterality of NEPHROLITHIASIS. Update the eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 12:03:22
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 13:45:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 13:45:55
Data point term sent to Coder	System	28 Sep 2020 20:06:50
Query 'Per DM CLR: Please specify laterality of NEPHROLITHIASIS. Update the eCRF as appropriate.' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4)	28 Sep 2020 20:06:42
Coding entries removed.	Afifah Ayub (b) (4)	28 Sep 2020 20:06:12
User entered 'NEPHROLITHIASIS (left)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	28 Sep 2020 20:06:12
User opened query 'Per DM CLR: Please specify laterality of NEPHROLITHIASIS. Update the eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 13:39:44
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis - version MedDRA\23.0.	Coder Import (b) (4)	04 Aug 2020 17:31:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Aug 2020 17:31:03
Data point term sent to Coder	System	04 Aug 2020 17:29:58
User entered 'Nephrolithiasis'	Afifah Ayub (b) (4)	04 Aug 2020 17:29:03

US3212028

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'UN Oct 2017'	Afifah Ayub (b) (4)	04 Aug 2020 17:29:03

US3212028

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '0'	Afifah Ayub (b) (4)	04 Aug 2020 17:29:03

US3212028

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Aug 2020 17:29:03

US3212028

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'UN Oct 2017'	Afifah Ayub (b) (4)	04 Aug 2020 17:29:03

US3212028

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '0'	Afifah Ayub (b) (4)	04 Aug 2020 17:29:03

US3212028

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered 'Oct 2017'	System	04 Aug 2020 17:29:03

US3212028

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered '2017'	System	04 Aug 2020 17:29:03

US3212028

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered 'Oct 2017'	System	04 Aug 2020 17:29:03

US3212028

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered '2017'	System	04 Aug 2020 17:29:03

US3212028

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:45:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Musculoskeletal and connective tissue disorders congenital, HLT: Musculoskeletal and connective tissue disorders of limbs congenital, PT: Developmental hip dysplasia, LLT: Hip dysplasia - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 05:02:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 05:02:21
Data point term sent to Coder	System	13 Oct 2020 19:15:26
User entered 'Genetic bilateral hip dysplasia'	Nirja Shah (b) (4)	13 Oct 2020 19:15:19

US3212028

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered (b) (6) 1953'	Nirja Shah (b) (4)	13 Oct 2020 19:15:19

US3212028

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '0'	Nirja Shah (b) (4)	13 Oct 2020 19:15:19

US3212028

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:45:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'No (N)'	Nirja Shah (b) (4)	13 Oct 2020 19:15:19

US3212028

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '10 Apr 2018'	Nirja Shah (b) (4)	13 Oct 2020 19:15:19

US3212028

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:45:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '0'	Nirja Shah (b) (4)	13 Oct 2020 19:15:19

US3212028

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:45:33

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered (b) (6) 1953'	System	13 Oct 2020 19:15:19

US3212028

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered '1953'	System	13 Oct 2020 19:15:19

US3212028

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered 'Apr 2018'	System	13 Oct 2020 19:15:19

US3212028

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered '2018'	System	13 Oct 2020 19:15:19

US3212028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Aug 2020 17:30:56

US3212028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '04 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	03 Dec 2020 18:38:39
User entered '4 Aug 2020'	Afifah Ayub (b) (4)	04 Aug 2020 17:30:56

US3212028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '11:48'	Afifah Ayub (b) (4)	04 Aug 2020 17:30:56

US3212028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered '04 Aug 2020 11:48'	System	03 Dec 2020 18:38:39
User entered '4 Aug 2020 11:48'	System	04 Aug 2020 17:30:56

US3212028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '68' in	Afifah Ayub (b) (4)	04 Aug 2020 17:30:56
DataPoint set to visible.	(b) (4) System	04 Aug 2020 17:26:54

US3212028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '172' lb	Afifah Ayub (b) (4)	04 Aug 2020 17:30:56
DataPoint set to visible.	(b) (4) System	04 Aug 2020 17:26:54

US3212028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
Amendment Manager: User entered '26.20719'	System	16 Sep 2020 23:42:45
User entered '26.2'	System	04 Aug 2020 17:30:56
DataPoint set to visible.	System	04 Aug 2020 17:26:54

US3212028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered 'kg/m2'	System	04 Aug 2020 17:30:56
DataPoint set to visible.	System	04 Aug 2020 17:26:54

US3212028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4)	20 Aug 2020 18:06:55
User entered '97.5' F	Afifah Ayub (b) (4)	04 Aug 2020 17:30:56

US3212028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 17:06:13
User entered 'Other (Other)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	20 Aug 2020 18:06:55
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	04 Aug 2020 17:30:56

US3212028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 17:06:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4)	20 Aug 2020 18:06:55
User entered empty.	Afifah Ayub (b) (4)	04 Aug 2020 17:30:56

US3212028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4)	20 Aug 2020 18:06:55
User entered '65'	Afifah Ayub (b) (4)	04 Aug 2020 17:30:56

US3212028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered 'bpm'	System	04 Aug 2020 17:30:56

US3212028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4)	20 Aug 2020 18:06:55
User entered '15'	Afifah Ayub (b) (4)	04 Aug 2020 17:30:56

US3212028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered 'breaths/min'	System	04 Aug 2020 17:30:56

US3212028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4)	20 Aug 2020 18:06:55
User entered '128'	Afifah Ayub (b) (4)	04 Aug 2020 17:30:56

US3212028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered 'mmHg'	System	04 Aug 2020 17:30:56

US3212028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4)	20 Aug 2020 18:06:55
User entered '73'	Afifah Ayub (b) (4)	04 Aug 2020 17:30:56

US3212028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User entered 'mmHg'	System	04 Aug 2020 17:30:56

US3212028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47

US3212028

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47

US3212028

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Aug 2020 17:31:15

US3212028

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '04 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	03 Dec 2020 18:38:46
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 09:29:02
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		01 Sep 2020 18:02:05
User entered '4 Aug 2020'	Afifah Ayub (b) (4)	04 Aug 2020 17:31:15

US3212028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

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 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Aug 2020 17:32:36

US3212028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

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 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Aug 2020 17:32:36

US3212028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

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 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Aug 2020 17:32:36

US3212028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

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 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Aug 2020 17:32:36

US3212028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

[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 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Aug 2020 17:32:36

US3212028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

[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 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Aug 2020 17:32:36

US3212028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

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 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Aug 2020 17:32:36

US3212028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

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 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Aug 2020 17:32:36

US3212028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

[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 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Aug 2020 17:32:36

US3212028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

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 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Aug 2020 17:32:36

US3212028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

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 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Aug 2020 17:32:36

US3212028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Aug 2020 17:32:36

US3212028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Retired'	Afifah Ayub (b) (4)	04 Aug 2020 17:32:36

US3212028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '0'	Afifah Ayub (b) (4)	04 Aug 2020 17:32:36

US3212028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '0'	Afifah Ayub (b) (4)	04 Aug 2020 17:32:36

US3212028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

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 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '0'	Afifah Ayub (b) (4)	04 Aug 2020 17:32:36

US3212028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

[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 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '0'	Afifah Ayub (b) (4)	04 Aug 2020 17:32:36

US3212028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

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 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '0'	Afifah Ayub (b) (4)	04 Aug 2020 17:32:36

US3212028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '0'	Afifah Ayub (b) (4)	04 Aug 2020 17:32:36

US3212028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'I'	Afifah Ayub (b) (4)	04 Aug 2020 17:32:36

US3212028

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:08:47
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Participant attended large group events in the past few weeks (e.g., wedding, places of worship, concert). Cohabitation/living in the same household as someone working at a high occupational risk job.'	Afifah Ayub (b) (4)	04 Aug 2020 17:32:36

US3212028

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Aug 2020 17:32:49

US3212028

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '04 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	10 Nov 2020 14:04:21
User entered '4 Aug 2020'	Afifah Ayub (b) (4)	04 Aug 2020 17:32:49

US3212028

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4)	04 Aug 2020 17:32:49

US3212028

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'VISIT1'	System	04 Aug 2020 17:32:49

US3212028

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '04 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 17:44:26

US3212028

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:00:34
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:00:33
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 17:44:26
User entered '184484' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 17:44:26

US3212028

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 17:44:26

US3212028

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Aug 2020 17:50:45

US3212028

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Aug 2020 17:50:45

US3212028

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Aug 2020 17:50:45

US3212028

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:33

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Aug 2020 17:50:45

US3212028

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:33

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Aug 2020 17:50:45

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User accepted default value 'Pre-Dose (PREDOSE)'	Afifah Ayub (b) (4) (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '04 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Dec 2020 19:05:00
User entered '4 Aug 2020'	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '11:48'	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered '04 Aug 2020 11:48'	System	04 Dec 2020 19:05:00
User entered '4 Aug 2020 11:48'	System	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '97.5' F	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty.	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '65'	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'bpm'	System	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '15'	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'breaths/min'	System	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '128'	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'mmHg'	System	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '73'	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'mmHg'	System	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User accepted default value 'Post-Dose (POSTDOSE)'	Afifah Ayub (b) (4) (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '04 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Dec 2020 19:05:00
User entered '4 Aug 2020'	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
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 11:42:23
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 13:29:29
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 13:29:16
User entered '13:50'	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered '04 Aug 2020 13:50'	System	04 Dec 2020 19:05:00
User entered '4 Aug 2020 13:50'	System	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '97.7' F	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty.	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '56'	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'bpm'	System	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '15'	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'breaths/min'	System	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '143'	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'mmHg'	System	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '83'	Afifah Ayub (b) (4)	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'mmHg'	System	05 Aug 2020 13:29:16

US3212028

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	20 Aug 2020 18:07:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Aug 2020 17:50:02

US3212028

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	20 Aug 2020 18:07:10
User entered '4 Aug 2020'	Afifah Ayub (b) (4)	04 Aug 2020 17:50:02

US3212028

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Nirja Shah (b) (4)	04 Aug 2020 18:08:16

US3212028

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty.	Nirja Shah (b) (4)	04 Aug 2020 18:08:16

US3212028

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty.	Nirja Shah (b) (4)	04 Aug 2020 18:08:16

US3212028

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 18:08:16

US3212028

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '04 Aug 2020'	Nirja Shah (b) (4)	04 Aug 2020 18:08:16

US3212028

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '13:06'	Nirja Shah (b) (4)	04 Aug 2020 18:08:16

US3212028

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered '04 Aug 2020 13:06'	System	04 Aug 2020 18:08:16

US3212028

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Left Arm (LEFT ARM)'	Nirja Shah (b) (4)	04 Aug 2020 18:08:16

US3212028

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'ONCE'	System	04 Aug 2020 18:08:16

US3212028

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 18:08:16

US3212028

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Aug 2020 17:51:25

US3212028

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '04 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	03 Dec 2020 18:38:07
User entered '4 Aug 2020'	Afifah Ayub (b) (4)	04 Aug 2020 17:51:25

US3212028

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '12:27'	Afifah Ayub (b) (4)	04 Aug 2020 17:51:25

US3212028

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered '04 Aug 2020 12:27'	System	03 Dec 2020 18:38:07
User entered '4 Aug 2020 12:27'	System	04 Aug 2020 17:51:25

US3212028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:45:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '04 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Dec 2020 19:05:18
User entered '4 Aug 2020'	Afifah Ayub (b) (4)	04 Aug 2020 17:52:01

US3212028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:45:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:52:01

US3212028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:45:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Aug 2020 17:52:01

US3212028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:45:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '12:21'	Afifah Ayub (b) (4)	04 Aug 2020 17:52:01

US3212028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered '04 Aug 2020 12:21'	System	04 Dec 2020 19:05:18
User entered '4 Aug 2020 12:21'	System	04 Aug 2020 17:52:01

US3212028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:45:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Afifah Ayub (b) (4)	04 Aug 2020 17:52:01

US3212028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:45:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Aug 2020 19:55:56
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Aug 2020 17:52:01

US3212028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:45:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Aug 2020 19:55:56
User entered '12:21'	Afifah Ayub (b) (4)	04 Aug 2020 17:52:01

US3212028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered empty.	System	25 Aug 2020 19:55:56
User entered '4 Aug 2020 12:21'	System	04 Aug 2020 17:52:01

US3212028

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	18 Aug 2020 19:25:40

US3212028

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'I'	System	18 Aug 2020 19:25:40

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T13:42:10', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '7a943ce0-b7c1-47e8-a7af-8563152398c4' User entered 'Yes (Y)'	System	04 Aug 2020 18:42:28
	System	04 Aug 2020 18:42:28

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T13:42:17', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '7a943ce0-b7c1-47e8-a7af-8563152398c4' User entered '97.7'	System	04 Aug 2020 18:42:28
	System	04 Aug 2020 18:42:28

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T13:42:21', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '7a943ce0-b7c1-47e8-a7af-8563152398c4' User entered 'No (N)'	System	04 Aug 2020 18:42:28
	System	04 Aug 2020 18:42:28

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T13:42:26', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '7a943ce0-b7c1-47e8-a7af-8563152398c4' User entered '04 Aug 2020 13:42'	System	04 Aug 2020 18:42:28
	System	04 Aug 2020 18:42:28

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '04 Aug 2020 13:26'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '04 Aug 2020 15:56'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T19:56:19', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '6e903c22-614a-400f-8368-fefcbdedd43f' User entered 'Yes (Y)'	System	05 Aug 2020 00:57:20
	System	05 Aug 2020 00:57:20

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T19:56:59', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '6e903c22-614a-400f-8368-fefcbdedd43f' User entered '97.9'	System	05 Aug 2020 00:57:20
	System	05 Aug 2020 00:57:20

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T19:57:02', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '6e903c22-614a-400f-8368-fefcbdedd43f' User entered 'No (N)'	System	05 Aug 2020 00:57:20
	System	05 Aug 2020 00:57:20

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T19:57:08', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '6e903c22-614a-400f-8368-fefcbdedd43f' User entered '04 Aug 2020 19:57'	System	05 Aug 2020 00:57:20
	System	05 Aug 2020 00:57:20

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '04 Aug 2020 16:51'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 2'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-05T18:03:10', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '537d92d1-9fa9-4438-ab55-7447f4b65d74' User entered 'Yes (Y)'	System	05 Aug 2020 23:03:24
	System	05 Aug 2020 23:03:24

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-05T18:03:15', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '537d92d1-9fa9-4438-ab55-7447f4b65d74' User entered '97.8'	System	05 Aug 2020 23:03:24
	System	05 Aug 2020 23:03:24

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-05T18:03:19', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '537d92d1-9fa9-4438-ab55-7447f4b65d74' User entered 'No (N)'	System	05 Aug 2020 23:03:24
	System	05 Aug 2020 23:03:24

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-05T18:03:23', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '537d92d1-9fa9-4438-ab55-7447f4b65d74' User entered '05 Aug 2020 18:03'	System	05 Aug 2020 23:03:24
	System	05 Aug 2020 23:03:24

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 3'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-06T15:45:57', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '2c2d42f9-891b-4bd7-b49f-72f5ea882c0d' User entered 'Yes (Y)'	System	06 Aug 2020 20:46:13
	System	06 Aug 2020 20:46:13

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-06T15:46:01', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '2c2d42f9-891b-4bd7-b49f-72f5ea882c0d' User entered '97.7'	System	06 Aug 2020 20:46:13
	System	06 Aug 2020 20:46:13

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-06T15:46:04', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '2c2d42f9-891b-4bd7-b49f-72f5ea882c0d' User entered 'No (N)'	System	06 Aug 2020 20:46:13
	System	06 Aug 2020 20:46:13

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-06T15:46:08', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '2c2d42f9-891b-4bd7-b49f-72f5ea882c0d' User entered '06 Aug 2020 15:46'	System	06 Aug 2020 20:46:13
	System	06 Aug 2020 20:46:13

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 4'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-07T18:06:17', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '65690a8f-25b8-4bc2-98ed-ee21442c624e' User entered 'Yes (Y)'	System	07 Aug 2020 23:09:23
	System	07 Aug 2020 23:09:23

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-07T18:09:10', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '65690a8f-25b8-4bc2-98ed-ee21442c624e' User entered '97.0'	System	07 Aug 2020 23:09:23
	System	07 Aug 2020 23:09:23

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-07T18:09:13', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '65690a8f-25b8-4bc2-98ed-ee21442c624e' User entered 'No (N)'	System	07 Aug 2020 23:09:23
	System	07 Aug 2020 23:09:23

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-07T18:09:18', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '65690a8f-25b8-4bc2-98ed-ee21442c624e' User entered '07 Aug 2020 18:09'	System	07 Aug 2020 23:09:23
	System	07 Aug 2020 23:09:23

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 5'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-08T16:33:50', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '72aa01ba-7f56-42d8-a858-109bb97dc083' User entered 'Yes (Y)'	System	08 Aug 2020 21:34:06
	System	08 Aug 2020 21:34:06

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-08T16:33:55', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '72aa01ba-7f56-42d8-a858-109bb97dc083' User entered '97.7'	System	08 Aug 2020 21:34:06
	System	08 Aug 2020 21:34:06

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-08T16:33:59', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '72aa01ba-7f56-42d8-a858-109bb97dc083'	System	08 Aug 2020 21:34:06
User entered 'No (N)'	System	08 Aug 2020 21:34:06

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-08T16:34:02', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '72aa01ba-7f56-42d8-a858-109bb97dc083'	System	08 Aug 2020 21:34:06
User entered '08 Aug 2020 16:34'	System	08 Aug 2020 21:34:06

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 6'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-09T16:53:19', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'f951eb88-0bba-4bce-a943-f2535102589b' User entered 'Yes (Y)'	System	09 Aug 2020 21:53:32
	System	09 Aug 2020 21:53:32

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-09T16:53:23', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'f951eb88-0bba-4bce-a943-f2535102589b' User entered '97.6'	System	09 Aug 2020 21:53:32
	System	09 Aug 2020 21:53:32

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-09T16:53:26', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'f951eb88-0bba-4bce-a943-f2535102589b' User entered 'No (N)'	System	09 Aug 2020 21:53:32
	System	09 Aug 2020 21:53:32

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-09T16:53:29', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'f951eb88-0bba-4bce-a943-f2535102589b' User entered '09 Aug 2020 16:53'	System	09 Aug 2020 21:53:32
	System	09 Aug 2020 21:53:32

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 7'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-10T18:07:11', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '26bccc4a-bb6f-4b05-bf37-7ba57126dac1' User entered 'Yes (Y)'	System	10 Aug 2020 23:08:02
	System	10 Aug 2020 23:08:02

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-10T18:07:47', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '26bccc4a-bb6f-4b05-bf37-7ba57126dac1' User entered '97.9'	System	10 Aug 2020 23:08:02
	System	10 Aug 2020 23:08:02

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-10T18:07:50', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '26bccc4a-bb6f-4b05-bf37-7ba57126dac1' User entered 'No (N)'	System	10 Aug 2020 23:08:02
	System	10 Aug 2020 23:08:02

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-10T18:07:54', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '26bccc4a-bb6f-4b05-bf37-7ba57126dac1' User entered '10 Aug 2020 18:07'	System	10 Aug 2020 23:08:02
	System	10 Aug 2020 23:08:02

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T13:42:59', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '6208fd36-10ca-41ea-9543-a29ce87aeb2c' User entered 'None (1)'	System	04 Aug 2020 18:43:37
	System	04 Aug 2020 18:43:37

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T13:43:18', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '6208fd36-10ca-41ea-9543-a29ce87aeb2c' User entered 'No (N)'	System	04 Aug 2020 18:43:37
	System	04 Aug 2020 18:43:37

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T13:43:27', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '6208fd36-10ca-41ea-9543-a29ce87aeb2c' User entered 'No (N)'	System	04 Aug 2020 18:43:37
	System	04 Aug 2020 18:43:37

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T13:43:31', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '6208fd36-10ca-41ea-9543-a29ce87aeb2c' User entered 'None (1)'	System	04 Aug 2020 18:43:37
	System	04 Aug 2020 18:43:37

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T13:43:36', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '6208fd36-10ca-41ea-9543-a29ce87aeb2c' User entered '04 Aug 2020 13:43'	System	04 Aug 2020 18:43:37
	System	04 Aug 2020 18:43:37

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '04 Aug 2020 13:26'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '04 Aug 2020 15:56'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T19:58:27', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e9d18086-061a-4794-b7d4-81f1579b30a0' User entered 'None (1)'	System	05 Aug 2020 00:58:46
	System	05 Aug 2020 00:58:46

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T19:58:30', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e9d18086-061a-4794-b7d4-81f1579b30a0'	System	05 Aug 2020 00:58:46
User entered 'No (N)'	System	05 Aug 2020 00:58:46

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T19:58:33', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e9d18086-061a-4794-b7d4-81f1579b30a0'	System	05 Aug 2020 00:58:46
User entered 'No (N)'	System	05 Aug 2020 00:58:46

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T19:58:36', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e9d18086-061a-4794-b7d4-81f1579b30a0'	System	05 Aug 2020 00:58:46
User entered 'None (1)'	System	05 Aug 2020 00:58:46

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T19:58:41', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e9d18086-061a-4794-b7d4-81f1579b30a0'	System	05 Aug 2020 00:58:46
User entered '04 Aug 2020 19:58'	System	05 Aug 2020 00:58:46

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '04 Aug 2020 16:51'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 2'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-05T18:03:28', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e8134264-3ad2-4a21-8540-40fb6895e60c'	System	05 Aug 2020 23:03:40
User entered 'None (1)'	System	05 Aug 2020 23:03:40

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-05T18:03:30', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e8134264-3ad2-4a21-8540-40fb6895e60c'	System	05 Aug 2020 23:03:40
User entered 'No (N)'	System	05 Aug 2020 23:03:40

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-05T18:03:33', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e8134264-3ad2-4a21-8540-40fb6895e60c'	System	05 Aug 2020 23:03:40
User entered 'No (N)'	System	05 Aug 2020 23:03:40

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-05T18:03:36', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e8134264-3ad2-4a21-8540-40fb6895e60c' User entered 'None (1)'	System	05 Aug 2020 23:03:40
	System	05 Aug 2020 23:03:40

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-05T18:03:38', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e8134264-3ad2-4a21-8540-40fb6895e60c' User entered '05 Aug 2020 18:03'	System	05 Aug 2020 23:03:40
	System	05 Aug 2020 23:03:40

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 3'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-06T15:46:12', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '93ddaf07-86ca-46e6-b1e7-296415e7a3c9'	System	06 Aug 2020 20:46:25
User entered 'None (1)'	System	06 Aug 2020 20:46:25

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-06T15:46:14', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '93ddaf07-86ca-46e6-b1e7-296415e7a3c9' User entered 'No (N)'	System	06 Aug 2020 20:46:25
	System	06 Aug 2020 20:46:25

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-06T15:46:17', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '93ddaf07-86ca-46e6-b1e7-296415e7a3c9' User entered 'No (N)'	System	06 Aug 2020 20:46:25
	System	06 Aug 2020 20:46:25

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-06T15:46:20', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '93ddaf07-86ca-46e6-b1e7-296415e7a3c9' User entered 'None (1)'	System	06 Aug 2020 20:46:25
	System	06 Aug 2020 20:46:25

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-06T15:46:23', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '93ddaf07-86ca-46e6-b1e7-296415e7a3c9'	System	06 Aug 2020 20:46:25
User entered '06 Aug 2020 15:46'	System	06 Aug 2020 20:46:25

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 4'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-07T18:09:22', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e2396b49-81dc-4a7d-8325-d44cc72ce186'	System	07 Aug 2020 23:09:36
User entered 'None (1)'	System	07 Aug 2020 23:09:36

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-07T18:09:25', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e2396b49-81dc-4a7d-8325-d44cc72ce186'	System	07 Aug 2020 23:09:36
User entered 'No (N)'	System	07 Aug 2020 23:09:36

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-07T18:09:27', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e2396b49-81dc-4a7d-8325-d44cc72ce186'	System	07 Aug 2020 23:09:36
User entered 'No (N)'	System	07 Aug 2020 23:09:36

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-07T18:09:30', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e2396b49-81dc-4a7d-8325-d44cc72ce186'	System	07 Aug 2020 23:09:36
User entered 'None (1)'	System	07 Aug 2020 23:09:36

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-07T18:09:33', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e2396b49-81dc-4a7d-8325-d44cc72ce186'	System	07 Aug 2020 23:09:36
User entered '07 Aug 2020 18:09'	System	07 Aug 2020 23:09:36

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 5'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-08T16:34:06', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '8cd08c33-037f-4892-bdd9-4b2acd0cb728'	System	08 Aug 2020 21:34:21
User entered 'None (1)'	System	08 Aug 2020 21:34:21

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-08T16:34:09', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '8cd08c33-037f-4892-bdd9-4b2acd0cb728'	System	08 Aug 2020 21:34:21
User entered 'No (N)'	System	08 Aug 2020 21:34:21

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-08T16:34:11', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '8cd08c33-037f-4892-bdd9-4b2acd0cb728'	System	08 Aug 2020 21:34:21
User entered 'No (N)'	System	08 Aug 2020 21:34:21

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-08T16:34:13', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '8cd08c33-037f-4892-bdd9-4b2acd0cb728' User entered 'None (1)'	System	08 Aug 2020 21:34:21
	System	08 Aug 2020 21:34:21

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-08T16:34:16', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '8cd08c33-037f-4892-bdd9-4b2acd0cb728' User entered '08 Aug 2020 16:34'	System	08 Aug 2020 21:34:21
	System	08 Aug 2020 21:34:21

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 6'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-09T16:53:32', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '55bcb7dd-7922-4428-a2bd-9f9dbf5aafa9' User entered 'None (1)'	System	09 Aug 2020 21:53:46
	System	09 Aug 2020 21:53:46

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-09T16:53:34', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '55bcb7dd-7922-4428-a2bd-9f9dbf5aafa9'	System	09 Aug 2020 21:53:46
User entered 'No (N)'	System	09 Aug 2020 21:53:46

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-09T16:53:37', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '55bcb7dd-7922-4428-a2bd-9f9dbf5aafa9'	System	09 Aug 2020 21:53:46
User entered 'No (N)'	System	09 Aug 2020 21:53:46

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-09T16:53:39', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '55bcb7dd-7922-4428-a2bd-9f9dbf5aafa9' User entered 'None (1)'	System	09 Aug 2020 21:53:46
	System	09 Aug 2020 21:53:46

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-09T16:53:42', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '55bcb7dd-7922-4428-a2bd-9f9dbf5aafa9' User entered '09 Aug 2020 16:53'	System	09 Aug 2020 21:53:46
	System	09 Aug 2020 21:53:46

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 7'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-10T18:07:57', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '63153fc6-2a9a-4865-aaf5-7c41e4fb9257'	System	10 Aug 2020 23:08:38
User entered 'None (1)'	System	10 Aug 2020 23:08:38

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-10T18:08:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '63153fc6-2a9a-4865-aaf5-7c41e4fb9257'	System	10 Aug 2020 23:08:38
User entered 'No (N)'	System	10 Aug 2020 23:08:38

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-10T18:08:02', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '63153fc6-2a9a-4865-aaf5-7c41e4fb9257'	System	10 Aug 2020 23:08:38
User entered 'No (N)'	System	10 Aug 2020 23:08:38

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-10T18:08:05', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '63153fc6-2a9a-4865-aaf5-7c41e4fb9257'	System	10 Aug 2020 23:08:38
User entered 'None (1)'	System	10 Aug 2020 23:08:38

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-10T18:08:08', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '63153fc6-2a9a-4865-aaf5-7c41e4fb9257'	System	10 Aug 2020 23:08:38
User entered '10 Aug 2020 18:08'	System	10 Aug 2020 23:08:38

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T13:43:42', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'cc17421a-c0fe-40f0-9f5a-6835dc671a50' User entered 'None (0)'	System	04 Aug 2020 18:44:09
	System	04 Aug 2020 18:44:09

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T13:43:45', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'cc17421a-c0fe-40f0-9f5a-6835dc671a50' User entered 'None (0)'	System	04 Aug 2020 18:44:09
	System	04 Aug 2020 18:44:09

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T13:43:47', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'cc17421a-c0fe-40f0-9f5a-6835dc671a50' User entered 'None (0)'	System	04 Aug 2020 18:44:09
	System	04 Aug 2020 18:44:09

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T13:43:50', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'cc17421a-c0fe-40f0-9f5a-6835dc671a50' User entered 'None (0)'	System	04 Aug 2020 18:44:09
	System	04 Aug 2020 18:44:09

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T13:43:52', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'cc17421a-c0fe-40f0-9f5a-6835dc671a50' User entered 'None (0)'	System	04 Aug 2020 18:44:09
	System	04 Aug 2020 18:44:09

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T13:43:54', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'cc17421a-c0fe-40f0-9f5a-6835dc671a50' User entered 'None (0)'	System	04 Aug 2020 18:44:09
	System	04 Aug 2020 18:44:09

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T13:44:04', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'cc17421a-c0fe-40f0-9f5a-6835dc671a50'	System	04 Aug 2020 18:44:09
User entered 'No (N)'	System	04 Aug 2020 18:44:09

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T13:44:07', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'cc17421a-c0fe-40f0-9f5a-6835dc671a50'	System	04 Aug 2020 18:44:09
User entered '04 Aug 2020 13:44'	System	04 Aug 2020 18:44:09

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
User entered '04 Aug 2020 13:26'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
User entered '04 Aug 2020 15:56'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T19:58:45', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '0d8e2040-d125-4df0-ad9b-3aea0bf7dcda' User entered 'None (0)'	System	05 Aug 2020 00:59:12
	System	05 Aug 2020 00:59:12

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T19:58:48', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '0d8e2040-d125-4df0-ad9b-3aea0bf7dcda' User entered 'None (0)'	System	05 Aug 2020 00:59:12
	System	05 Aug 2020 00:59:12

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T19:58:51', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '0d8e2040-d125-4df0-ad9b-3aea0bf7dcda' User entered 'None (0)'	System	05 Aug 2020 00:59:12
	System	05 Aug 2020 00:59:12

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T19:58:54', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '0d8e2040-d125-4df0-ad9b-3aea0bf7dcda' User entered 'None (0)'	System	05 Aug 2020 00:59:12
	System	05 Aug 2020 00:59:12

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T19:58:56', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '0d8e2040-d125-4df0-ad9b-3aea0bf7dcda' User entered 'None (0)'	System	05 Aug 2020 00:59:12
	System	05 Aug 2020 00:59:12

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T19:58:58', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '0d8e2040-d125-4df0-ad9b-3aea0bf7dcda' User entered 'None (0)'	System	05 Aug 2020 00:59:12
	System	05 Aug 2020 00:59:12

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T19:59:04', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '0d8e2040-d125-4df0-ad9b-3aea0bf7dcda' User entered 'No (N)'	System	05 Aug 2020 00:59:12
	System	05 Aug 2020 00:59:12

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-04T19:59:07', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '0d8e2040-d125-4df0-ad9b-3aea0bf7dcda' User entered '04 Aug 2020 19:59'	System	05 Aug 2020 00:59:12
	System	05 Aug 2020 00:59:12

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
User entered '04 Aug 2020 16:51'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 2'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-05T18:03:42', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '2b666c04-e584-43f2-9f74-07597bb07c4f' User entered 'None (0)'	System	05 Aug 2020 23:04:04
	System	05 Aug 2020 23:04:04

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-05T18:03:45', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '2b666c04-e584-43f2-9f74-07597bb07c4f' User entered 'None (0)'	System	05 Aug 2020 23:04:04
	System	05 Aug 2020 23:04:04

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-05T18:03:48', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '2b666c04-e584-43f2-9f74-07597bb07c4f' User entered 'None (0)'	System	05 Aug 2020 23:04:04
	System	05 Aug 2020 23:04:04

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-05T18:03:51', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '2b666c04-e584-43f2-9f74-07597bb07c4f' User entered 'None (0)'	System	05 Aug 2020 23:04:04
	System	05 Aug 2020 23:04:04

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-05T18:03:54', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '2b666c04-e584-43f2-9f74-07597bb07c4f' User entered 'None (0)'	System	05 Aug 2020 23:04:04
	System	05 Aug 2020 23:04:04

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-05T18:03:55', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '2b666c04-e584-43f2-9f74-07597bb07c4f' User entered 'None (0)'	System	05 Aug 2020 23:04:04
	System	05 Aug 2020 23:04:04

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

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 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-05T18:03:59', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '2b666c04-e584-43f2-9f74-07597bb07c4f' User entered 'No (N)'	System	05 Aug 2020 23:04:04
	System	05 Aug 2020 23:04:04

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-05T18:04:02', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '2b666c04-e584-43f2-9f74-07597bb07c4f' User entered '05 Aug 2020 18:04'	System	05 Aug 2020 23:04:04
	System	05 Aug 2020 23:04:04

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 3'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-06T15:46:27', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '61d32620-76bb-4a09-a78e-aae017e3b810' User entered 'None (0)'	System	06 Aug 2020 20:46:57
	System	06 Aug 2020 20:46:57

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-06T15:46:30', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '61d32620-76bb-4a09-a78e-aae017e3b810' User entered 'None (0)'	System	06 Aug 2020 20:46:57
	System	06 Aug 2020 20:46:57

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-06T15:46:32', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '61d32620-76bb-4a09-a78e-aae017e3b810' User entered 'None (0)'	System	06 Aug 2020 20:46:57
	System	06 Aug 2020 20:46:57

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-06T15:46:35', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '61d32620-76bb-4a09-a78e-aae017e3b810' User entered 'None (0)'	System	06 Aug 2020 20:46:57
	System	06 Aug 2020 20:46:57

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-06T15:46:37', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '61d32620-76bb-4a09-a78e-aae017e3b810' User entered 'None (0)'	System	06 Aug 2020 20:46:57
	System	06 Aug 2020 20:46:57

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-06T15:46:39', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '61d32620-76bb-4a09-a78e-aae017e3b810' User entered 'None (0)'	System	06 Aug 2020 20:46:57
	System	06 Aug 2020 20:46:57

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

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 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-06T15:46:45', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '61d32620-76bb-4a09-a78e-aae017e3b810' User entered 'No (N)'	System	06 Aug 2020 20:46:57
	System	06 Aug 2020 20:46:57

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-06T15:46:47', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '61d32620-76bb-4a09-a78e-aae017e3b810' User entered '06 Aug 2020 15:46'	System	06 Aug 2020 20:46:57
	System	06 Aug 2020 20:46:57

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 4'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-07T18:09:37', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e51c55f6-ed43-4535-b4db-6aec772e3844' User entered 'None (0)'	System	08 Aug 2020 21:33:43
	System	08 Aug 2020 21:33:43

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-07T18:09:39', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e51c55f6-ed43-4535-b4db-6aec772e3844' User entered 'None (0)'	System	08 Aug 2020 21:33:43
	System	08 Aug 2020 21:33:43

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-07T18:09:41', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e51c55f6-ed43-4535-b4db-6aec772e3844' User entered 'None (0)'	System	08 Aug 2020 21:33:43
	System	08 Aug 2020 21:33:43

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-07T18:09:44', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e51c55f6-ed43-4535-b4db-6aec772e3844' User entered 'None (0)'	System	08 Aug 2020 21:33:43
	System	08 Aug 2020 21:33:43

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-07T18:09:46', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e51c55f6-ed43-4535-b4db-6aec772e3844' User entered 'None (0)'	System	08 Aug 2020 21:33:43
	System	08 Aug 2020 21:33:43

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-07T18:09:49', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e51c55f6-ed43-4535-b4db-6aec772e3844' User entered 'None (0)'	System	08 Aug 2020 21:33:43
	System	08 Aug 2020 21:33:43

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

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 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-07T18:09:54', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e51c55f6-ed43-4535-b4db-6aec772e3844'	System	08 Aug 2020 21:33:43
User entered 'No (N)'	System	08 Aug 2020 21:33:43

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-07T18:09:57', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e51c55f6-ed43-4535-b4db-6aec772e3844'	System	08 Aug 2020 21:33:43
User entered '07 Aug 2020 18:09'	System	08 Aug 2020 21:33:43

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 5'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-08T16:34:21', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '35a3ad73-9ed5-4008-8cc8-0502e3d48f4e' User entered 'None (0)'	System	08 Aug 2020 21:34:37
	System	08 Aug 2020 21:34:37

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-08T16:34:23', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '35a3ad73-9ed5-4008-8cc8-0502e3d48f4e' User entered 'None (0)'	System	08 Aug 2020 21:34:37
	System	08 Aug 2020 21:34:37

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-08T16:34:25', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '35a3ad73-9ed5-4008-8cc8-0502e3d48f4e' User entered 'None (0)'	System	08 Aug 2020 21:34:37
	System	08 Aug 2020 21:34:37

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-08T16:34:26', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '35a3ad73-9ed5-4008-8cc8-0502e3d48f4e' User entered 'None (0)'	System	08 Aug 2020 21:34:37
	System	08 Aug 2020 21:34:37

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-08T16:34:28', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '35a3ad73-9ed5-4008-8cc8-0502e3d48f4e' User entered 'None (0)'	System	08 Aug 2020 21:34:37
	System	08 Aug 2020 21:34:37

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-08T16:34:30', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '35a3ad73-9ed5-4008-8cc8-0502e3d48f4e' User entered 'None (0)'	System	08 Aug 2020 21:34:37
	System	08 Aug 2020 21:34:37

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

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 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-08T16:34:33', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '35a3ad73-9ed5-4008-8cc8-0502e3d48f4e' User entered 'No (N)'	System	08 Aug 2020 21:34:37
	System	08 Aug 2020 21:34:37

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-08T16:34:35', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '35a3ad73-9ed5-4008-8cc8-0502e3d48f4e' User entered '08 Aug 2020 16:34'	System	08 Aug 2020 21:34:37
	System	08 Aug 2020 21:34:37

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 6'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-09T16:53:46', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'bb194e8a-88ce-42ec-9843-6837c6608122' User entered 'None (0)'	System	09 Aug 2020 21:54:07
	System	09 Aug 2020 21:54:07

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-09T16:53:48', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'bb194e8a-88ce-42ec-9843-6837c6608122' User entered 'None (0)'	System	09 Aug 2020 21:54:07
	System	09 Aug 2020 21:54:07

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-09T16:53:50', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'bb194e8a-88ce-42ec-9843-6837c6608122' User entered 'None (0)'	System	09 Aug 2020 21:54:07
	System	09 Aug 2020 21:54:07

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-09T16:53:52', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'bb194e8a-88ce-42ec-9843-6837c6608122' User entered 'None (0)'	System	09 Aug 2020 21:54:07
	System	09 Aug 2020 21:54:07

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-09T16:53:55', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'bb194e8a-88ce-42ec-9843-6837c6608122' User entered 'None (0)'	System	09 Aug 2020 21:54:07
	System	09 Aug 2020 21:54:07

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-09T16:53:57', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'bb194e8a-88ce-42ec-9843-6837c6608122' User entered 'None (0)'	System	09 Aug 2020 21:54:07
	System	09 Aug 2020 21:54:07

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

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 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-09T16:54:01', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'bb194e8a-88ce-42ec-9843-6837c6608122'	System	09 Aug 2020 21:54:07
User entered 'No (N)'	System	09 Aug 2020 21:54:07

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-09T16:54:03', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'bb194e8a-88ce-42ec-9843-6837c6608122'	System	09 Aug 2020 21:54:07
User entered '09 Aug 2020 16:54'	System	09 Aug 2020 21:54:07

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 7'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-10T18:08:12', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '5b0508f4-cb6c-4813-920d-6c273b3d1505' User entered 'None (0)'	System	10 Aug 2020 23:08:38
	System	10 Aug 2020 23:08:38

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-10T18:08:15', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '5b0508f4-cb6c-4813-920d-6c273b3d1505'	System	10 Aug 2020 23:08:38
User entered 'None (0)'	System	10 Aug 2020 23:08:38

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-10T18:08:18', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '5b0508f4-cb6c-4813-920d-6c273b3d1505' User entered 'None (0)'	System	10 Aug 2020 23:08:38
	System	10 Aug 2020 23:08:38

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-10T18:08:20', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '5b0508f4-cb6c-4813-920d-6c273b3d1505' User entered 'None (0)'	System	10 Aug 2020 23:08:38
	System	10 Aug 2020 23:08:38

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-10T18:08:22', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '5b0508f4-cb6c-4813-920d-6c273b3d1505' User entered 'None (0)'	System	10 Aug 2020 23:08:38
	System	10 Aug 2020 23:08:38

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-10T18:08:24', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '5b0508f4-cb6c-4813-920d-6c273b3d1505' User entered 'None (0)'	System	10 Aug 2020 23:08:38
	System	10 Aug 2020 23:08:38

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

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 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-10T18:08:27', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '5b0508f4-cb6c-4813-920d-6c273b3d1505'	System	10 Aug 2020 23:08:38
User entered 'No (N)'	System	10 Aug 2020 23:08:38

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE8C33F3-9C4D-4C04-AF22-2073E9CC283A)', Time: '2020-08-10T18:08:30', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '5b0508f4-cb6c-4813-920d-6c273b3d1505' User entered '10 Aug 2020 18:08'	System	10 Aug 2020 23:08:38
	System	10 Aug 2020 23:08:38

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 18:08:16

US3212028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:04
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Heather Leary (b) (4)	18 Aug 2020 20:21:47

US3212028

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '11 Aug 2020'	Heather Leary (b) (4)	18 Aug 2020 20:21:47

US3212028

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Contact Made (CONTACT MADE)'	Heather Leary (b) (4)	18 Aug 2020 20:21:47

US3212028

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty.	Heather Leary (b) (4)	18 Aug 2020 20:21:47

US3212028

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Heather Leary (b) (4)	18 Aug 2020 20:21:50

US3212028

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'I'	System	18 Aug 2020 20:21:50

US3212028

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Heather Leary (b) (4)	19 Aug 2020 14:03:18

US3212028

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '18 Aug 2020'	Heather Leary (b) (4)	19 Aug 2020 14:03:18

US3212028

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Contact Made (CONTACT MADE)'	Heather Leary (b) (4)	19 Aug 2020 14:03:18

US3212028

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty.	Heather Leary (b) (4)	19 Aug 2020 14:03:18

US3212028

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	26 Aug 2020 14:05:10

US3212028

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'I'	System	26 Aug 2020 14:05:10

US3212028

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	26 Aug 2020 14:05:29

US3212028

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '25 Aug 2020'	Laura Ngansop Djampou (b) (4)	26 Aug 2020 14:05:29

US3212028

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	26 Aug 2020 14:05:29

US3212028

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty.	Laura Ngansop Djampou (b) (4)	26 Aug 2020 14:05:29

US3212028

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	26 Aug 2020 18:33:26

US3212028

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'I'	System	26 Aug 2020 18:33:26

US3212028

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	01 Sep 2020 18:02:05

US3212028

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '01 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	03 Dec 2020 18:36:58
User entered '1 Sep 2020'	Afifah Ayub (b) (4)	01 Sep 2020 18:02:05

US3212028

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4)	01 Sep 2020 18:02:05

US3212028

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'VISIT2'	System	01 Sep 2020 18:02:05

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User accepted default value 'Pre-Dose (PREDOSE)'	Afifah Ayub (b) (4) (b) (4)	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '01 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	03 Dec 2020 18:37:10
User entered '1 Sep 2020'	Afifah Ayub (b) (4)	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 19:31:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).		03 Sep 2020 19:31:17
User entered '11:48' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Sep 2020 19:31:17
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 02:06:43
User entered empty.	Afifah Ayub (b) (4)	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered '01 Sep 2020 11:48'	System	03 Dec 2020 18:37:10
User entered '1 Sep 2020 11:48'	System	03 Sep 2020 19:31:17
User entered empty.	System	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '97.3' F	Afifah Ayub (b) (4)	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 19:31:37
Query 'Data is required. Please provide.' answered by System data change (Site from System).		03 Sep 2020 19:31:37
User entered 'Oral (Oral)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Sep 2020 19:31:37
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 02:06:43
User entered empty.	Afifah Ayub (b) (4)	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty.	Afifah Ayub (b) (4)	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '63'	Afifah Ayub (b) (4)	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'bpm'	System	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '15'	Afifah Ayub (b) (4)	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'breaths/min'	System	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '124'	Afifah Ayub (b) (4)	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'mmHg'	System	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '77'	Afifah Ayub (b) (4)	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'mmHg'	System	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User accepted default value 'Post-Dose (POSTDOSE)'	Afifah Ayub (b) (4) (b) (4)	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '01 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	03 Dec 2020 18:37:10
User entered '1 Sep 2020'	Afifah Ayub (b) (4)	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '13:09'	Afifah Ayub (b) (4)	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered '01 Sep 2020 13:09'	System	03 Dec 2020 18:37:10
User entered '1 Sep 2020 13:09'	System	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '96.9' F	Afifah Ayub (b) (4)	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty.	Afifah Ayub (b) (4)	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '56'	Afifah Ayub (b) (4)	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'bpm'	System	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '15'	Afifah Ayub (b) (4)	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'breaths/min'	System	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '147'	Afifah Ayub (b) (4)	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'mmHg'	System	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '77'	Afifah Ayub (b) (4)	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'mmHg'	System	02 Sep 2020 02:06:43

US3212028

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	01 Sep 2020 18:02:17

US3212028

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '01 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	03 Dec 2020 18:37:17
User entered '1 Sep 2020'	Afifah Ayub (b) (4)	01 Sep 2020 18:02:17

US3212028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Heather Leary (b) (4)	01 Sep 2020 17:56:37

US3212028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty.	Heather Leary (b) (4)	01 Sep 2020 17:56:37

US3212028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty.	Heather Leary (b) (4)	01 Sep 2020 17:56:37

US3212028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 17:56:37

US3212028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '01 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	03 Dec 2020 18:37:26
User entered '1 Sep 2020'	Heather Leary (b) (4)	01 Sep 2020 17:56:37

US3212028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '12:37'	Heather Leary (b) (4)	01 Sep 2020 17:56:37

US3212028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered '01 Sep 2020 12:37'	System	03 Dec 2020 18:37:26
User entered '1 Sep 2020 12:37'	System	01 Sep 2020 17:56:37

US3212028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Left Arm (LEFT ARM)'	Heather Leary (b) (4)	01 Sep 2020 17:56:37

US3212028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'ONCE'	System	01 Sep 2020 17:56:37

US3212028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 17:56:37

US3212028

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	01 Sep 2020 18:02:35

US3212028

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '01 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	03 Dec 2020 18:37:32
User entered '1 Sep 2020'	Afifah Ayub (b) (4)	01 Sep 2020 18:02:35

US3212028

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '12:22'	Afifah Ayub (b) (4)	01 Sep 2020 18:02:35

US3212028

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered '01 Sep 2020 12:22'	System	03 Dec 2020 18:37:32
User entered '1 Sep 2020 12:22'	System	01 Sep 2020 18:02:35

US3212028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:45:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '01 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	03 Dec 2020 18:37:37
User entered '1 Sep 2020'	Afifah Ayub (b) (4)	01 Sep 2020 18:03:02

US3212028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:45:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Afifah Ayub (b) (4)	01 Sep 2020 18:03:02

US3212028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:45:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	01 Sep 2020 18:03:02

US3212028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:45:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '12:18'	Afifah Ayub (b) (4)	01 Sep 2020 18:03:02

US3212028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered '01 Sep 2020 12:18'	System	03 Dec 2020 18:37:37
User entered '1 Sep 2020 12:18'	System	01 Sep 2020 18:03:02

US3212028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:45:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Afifah Ayub (b) (4)	01 Sep 2020 18:03:02

US3212028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:45:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'No (N)'	Afifah Ayub (b) (4)	01 Sep 2020 18:03:02

US3212028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:45:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty.	Afifah Ayub (b) (4)	01 Sep 2020 18:03:02

US3212028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered empty.	System	01 Sep 2020 18:03:02

US3212028

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	01 Sep 2020 18:03:08

US3212028

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'I'	System	01 Sep 2020 18:03:08

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	01 Sep 2020 17:56:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T13:10:45', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '578932d2-c698-4053-9017-948cdbdad83c' User entered 'Yes (Y)'	System	01 Sep 2020 18:11:06
	System	01 Sep 2020 18:11:06

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T13:10:51', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '578932d2-c698-4053-9017-948cdbdad83c' User entered '96.9'	System	01 Sep 2020 18:11:06
	System	01 Sep 2020 18:11:06

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T13:10:55', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '578932d2-c698-4053-9017-948cdbdad83c' User entered 'No (N)'	System	01 Sep 2020 18:11:06
	System	01 Sep 2020 18:11:06

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T13:11:01', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '578932d2-c698-4053-9017-948cbbdad83c' User entered '01 Sep 2020 13:11'	System	01 Sep 2020 18:11:06
	System	01 Sep 2020 18:11:06

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '01 Sep 2020 12:57'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '01 Sep 2020 15:27'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	01 Sep 2020 17:56:37
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T16:44:57', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'd3dbda3c-aba6-42bb-bb82-1dcf46ac9765' User entered 'Yes (Y)'	System	01 Sep 2020 21:45:14
	System	01 Sep 2020 21:45:14

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T16:45:03', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'd3dbda3c-aba6-42bb-bb82-1dcf46ac9765' User entered '97.9'	System	01 Sep 2020 21:45:14
	System	01 Sep 2020 21:45:14

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T16:45:06', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'd3dbda3c-aba6-42bb-bb82-1dcf46ac9765'	System	01 Sep 2020 21:45:14
User entered 'No (N)'	System	01 Sep 2020 21:45:14

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T16:45:10', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'd3dbda3c-aba6-42bb-bb82-1dcf46ac9765' User entered '01 Sep 2020 16:45'	System	01 Sep 2020 21:45:14
	System	01 Sep 2020 21:45:14

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '01 Sep 2020 16:22'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	01 Sep 2020 17:56:37
User entered 'Day 2'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-02T13:10:18', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '36bb7845-6d1e-4dfd-bdfd-b71f390b33bd' User entered 'Yes (Y)'	System	02 Sep 2020 18:10:46
	System	02 Sep 2020 18:10:46

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-02T13:10:24', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '36bb7845-6d1e-4dfd-bdfd-b71f390b33bd' User entered '100.4'	System	02 Sep 2020 18:10:46
	System	02 Sep 2020 18:10:46

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-02T13:10:27', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '36bb7845-6d1e-4dfd-bdfd-b71f390b33bd' User entered 'Yes (Y)'	System	02 Sep 2020 18:10:46
	System	02 Sep 2020 18:10:46

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'patient was contacted and medications updated' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 15:37:37
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-02T13:10:34', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '36bb7845-6d1e-4dfd-bdfd-b71f390b33bd' User entered '1'	Heather Leary (b) (4)	08 Sep 2020 15:47:18
	System	02 Sep 2020 18:10:46
	System	02 Sep 2020 18:10:46
	System	02 Sep 2020 18:10:46

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-02T13:10:34', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '36bb7845-6d1e-4dfd-bdfd-b71f390b33bd' User entered '0'	System	02 Sep 2020 18:10:46
	System	02 Sep 2020 18:10:46

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-02T13:10:43', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '36bb7845-6d1e-4dfd-bdfd-b71f390b33bd' User entered '02 Sep 2020 13:10'	System	02 Sep 2020 18:10:46
	System	02 Sep 2020 18:10:46

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	01 Sep 2020 17:56:37
User entered 'Day 3'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-03T12:58:22', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'db52b72a-3ee4-4c75-9369-d869c4d383a0' User entered 'Yes (Y)'	System	03 Sep 2020 17:58:45
	System	03 Sep 2020 17:58:45

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-03T12:58:37', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'db52b72a-3ee4-4c75-9369-d869c4d383a0' User entered '96.7'	System	03 Sep 2020 17:58:45
	System	03 Sep 2020 17:58:45

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-03T12:58:41', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'db52b72a-3ee4-4c75-9369-d869c4d383a0' User entered 'No (N)'	System	03 Sep 2020 17:58:45
	System	03 Sep 2020 17:58:45

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-03T12:58:44', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'db52b72a-3ee4-4c75-9369-d869c4d383a0' User entered '03 Sep 2020 12:58'	System	03 Sep 2020 17:58:45
	System	03 Sep 2020 17:58:45

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	01 Sep 2020 17:56:37
User entered 'Day 4'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-04T13:57:10', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '896b8bb4-4cad-4bfc-86f3-e44bed0ffd73' User entered 'Yes (Y)'	System	04 Sep 2020 18:57:24
	System	04 Sep 2020 18:57:24

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-04T13:57:16', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '896b8bb4-4cad-4bfc-86f3-e44bed0ffd73' User entered '97.9'	System	04 Sep 2020 18:57:24
	System	04 Sep 2020 18:57:24

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-04T13:57:19', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '896b8bb4-4cad-4bfc-86f3-e44bed0ffd73' User entered 'No (N)'	System	04 Sep 2020 18:57:24
	System	04 Sep 2020 18:57:24

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-04T13:57:22', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '896b8bb4-4cad-4bfc-86f3-e44bed0ffd73' User entered '04 Sep 2020 13:57'	System	04 Sep 2020 18:57:24
	System	04 Sep 2020 18:57:24

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	01 Sep 2020 17:56:37
User entered 'Day 5'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-05T14:07:48', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '354292f4-c394-4be3-ada4-8675e8d7ef60' User entered 'Yes (Y)'	System	05 Sep 2020 19:08:37
	System	05 Sep 2020 19:08:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-05T14:08:27', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '354292f4-c394-4be3-ada4-8675e8d7ef60' User entered '97.9'	System	05 Sep 2020 19:08:37
	System	05 Sep 2020 19:08:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-05T14:08:30', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '354292f4-c394-4be3-ada4-8675e8d7ef60' User entered 'No (N)'	System	05 Sep 2020 19:08:37
	System	05 Sep 2020 19:08:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-05T14:08:33', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '354292f4-c394-4be3-ada4-8675e8d7ef60' User entered '05 Sep 2020 14:08'	System	05 Sep 2020 19:08:37
	System	05 Sep 2020 19:08:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	01 Sep 2020 17:56:37
User entered 'Day 6'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-06T15:23:54', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '99c9e68b-87f9-483f-b9f8-fbfa4cbf7241' User entered 'Yes (Y)'	System	28 Sep 2020 15:57:00
	System	28 Sep 2020 15:57:00

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-06T15:23:59', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '99c9e68b-87f9-483f-b9f8-fbfa4cbf7241' User entered '97.7'	System	28 Sep 2020 15:57:00
	System	28 Sep 2020 15:57:00

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-06T15:24:02', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '99c9e68b-87f9-483f-b9f8-fbfa4cbf7241' User entered 'No (N)'	System	28 Sep 2020 15:57:00
	System	28 Sep 2020 15:57:00

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-06T15:24:05', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '99c9e68b-87f9-483f-b9f8-fbfa4cbf7241' User entered '06 Sep 2020 15:24'	System	28 Sep 2020 15:57:00
	System	28 Sep 2020 15:57:00

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	01 Sep 2020 17:56:37
User entered 'Day 7'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-07T13:37:55', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'f8834eb0-851f-4701-9dd8-d53f2bf713a8' User entered 'Yes (Y)'	System	28 Sep 2020 15:57:07
	System	28 Sep 2020 15:57:07

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-07T13:38:03', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'f8834eb0-851f-4701-9dd8-d53f2bf713a8' User entered '97.6'	System	28 Sep 2020 15:57:07
	System	28 Sep 2020 15:57:07

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-07T13:38:06', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'f8834eb0-851f-4701-9dd8-d53f2bf713a8' User entered 'No (N)'	System	28 Sep 2020 15:57:07
	System	28 Sep 2020 15:57:07

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-07T13:38:09', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'f8834eb0-851f-4701-9dd8-d53f2bf713a8' User entered '07 Sep 2020 13:38'	System	28 Sep 2020 15:57:07
	System	28 Sep 2020 15:57:07

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	01 Sep 2020 17:56:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T13:11:12', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'c66190f5-374c-46ab-9cb6-f30bb998eb43' User entered 'None (1)'	System	01 Sep 2020 18:12:05
	System	01 Sep 2020 18:12:05

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T13:11:52', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'c66190f5-374c-46ab-9cb6-f30bb998eb43' User entered 'No (N)'	System	01 Sep 2020 18:12:05
	System	01 Sep 2020 18:12:05

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T13:11:55', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'c66190f5-374c-46ab-9cb6-f30bb998eb43' User entered 'No (N)'	System	01 Sep 2020 18:12:05
	System	01 Sep 2020 18:12:05

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T13:11:59', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'c66190f5-374c-46ab-9cb6-f30bb998eb43' User entered 'None (1)'	System	01 Sep 2020 18:12:05
	System	01 Sep 2020 18:12:05

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T13:12:02', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'c66190f5-374c-46ab-9cb6-f30bb998eb43' User entered '01 Sep 2020 13:12'	System	01 Sep 2020 18:12:05
	System	01 Sep 2020 18:12:05

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '01 Sep 2020 12:57'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '01 Sep 2020 15:27'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	01 Sep 2020 17:56:37
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T16:45:14', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e9c04e06-b79d-4516-8a0e-510e0740e3ec' User entered 'None (1)'	System	01 Sep 2020 21:45:26
	System	01 Sep 2020 21:45:26

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T16:45:16', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e9c04e06-b79d-4516-8a0e-510e0740e3ec' User entered 'No (N)'	System	01 Sep 2020 21:45:26
	System	01 Sep 2020 21:45:26

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T16:45:19', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e9c04e06-b79d-4516-8a0e-510e0740e3ec' User entered 'No (N)'	System	01 Sep 2020 21:45:26
	System	01 Sep 2020 21:45:26

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T16:45:21', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e9c04e06-b79d-4516-8a0e-510e0740e3ec' User entered 'None (1)'	System	01 Sep 2020 21:45:26
	System	01 Sep 2020 21:45:26

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T16:45:23', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e9c04e06-b79d-4516-8a0e-510e0740e3ec' User entered '01 Sep 2020 16:45'	System	01 Sep 2020 21:45:26
	System	01 Sep 2020 21:45:26

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '01 Sep 2020 16:22'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	01 Sep 2020 17:56:37
User entered 'Day 2'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-02T13:10:57', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'd2746594-a708-4322-a533-e2195bc9800d' User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 18:11:12
	System	02 Sep 2020 18:11:12

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-02T13:11:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'd2746594-a708-4322-a533-e2195bc9800d' User entered 'No (N)'	System	02 Sep 2020 18:11:12
	System	02 Sep 2020 18:11:12

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-02T13:11:03', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'd2746594-a708-4322-a533-e2195bc9800d' User entered 'No (N)'	System	02 Sep 2020 18:11:12
	System	02 Sep 2020 18:11:12

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-02T13:11:06', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'd2746594-a708-4322-a533-e2195bc9800d' User entered 'None (1)'	System	02 Sep 2020 18:11:12
	System	02 Sep 2020 18:11:12

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-02T13:11:10', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'd2746594-a708-4322-a533-e2195bc9800d' User entered '02 Sep 2020 13:11'	System	02 Sep 2020 18:11:12
	System	02 Sep 2020 18:11:12

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	01 Sep 2020 17:56:37
User entered 'Day 3'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-03T12:58:49', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '5ef914e6-c068-45aa-a748-44dcd31a080a' User entered 'None (1)'	System	03 Sep 2020 17:59:04
	System	03 Sep 2020 17:59:04

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-03T12:58:52', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '5ef914e6-c068-45aa-a748-44dcd31a080a' User entered 'No (N)'	System	03 Sep 2020 17:59:04
	System	03 Sep 2020 17:59:04

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-03T12:58:54', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '5ef914e6-c068-45aa-a748-44dcd31a080a' User entered 'No (N)'	System	03 Sep 2020 17:59:04
	System	03 Sep 2020 17:59:04

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-03T12:58:57', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '5ef914e6-c068-45aa-a748-44dcd31a080a' User entered 'None (1)'	System	03 Sep 2020 17:59:04
	System	03 Sep 2020 17:59:04

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-03T12:58:59', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '5ef914e6-c068-45aa-a748-44dcd31a080a' User entered '03 Sep 2020 12:58'	System	03 Sep 2020 17:59:04
	System	03 Sep 2020 17:59:04

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	01 Sep 2020 17:56:37
User entered 'Day 4'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-04T13:57:27', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '99a3c176-063e-4782-9233-23a498da5b89'	System	04 Sep 2020 18:57:40
User entered 'None (1)'	System	04 Sep 2020 18:57:40

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-04T13:57:29', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '99a3c176-063e-4782-9233-23a498da5b89' User entered 'No (N)'	System	04 Sep 2020 18:57:40
	System	04 Sep 2020 18:57:40

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-04T13:57:32', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '99a3c176-063e-4782-9233-23a498da5b89' User entered 'No (N)'	System	04 Sep 2020 18:57:40
	System	04 Sep 2020 18:57:40

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-04T13:57:34', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '99a3c176-063e-4782-9233-23a498da5b89' User entered 'None (1)'	System	04 Sep 2020 18:57:40
	System	04 Sep 2020 18:57:40

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-04T13:57:37', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '99a3c176-063e-4782-9233-23a498da5b89' User entered '04 Sep 2020 13:57'	System	04 Sep 2020 18:57:40
	System	04 Sep 2020 18:57:40

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	01 Sep 2020 17:56:37
User entered 'Day 5'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-05T14:08:44', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '8c072f6a-2861-48e0-9b41-c2c8bd22d963' User entered 'None (1)'	System	05 Sep 2020 19:08:58
	System	05 Sep 2020 19:08:58

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-05T14:08:47', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '8c072f6a-2861-48e0-9b41-c2c8bd22d963' User entered 'No (N)'	System	05 Sep 2020 19:08:58
	System	05 Sep 2020 19:08:58

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-05T14:08:50', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '8c072f6a-2861-48e0-9b41-c2c8bd22d963' User entered 'No (N)'	System	05 Sep 2020 19:08:58
	System	05 Sep 2020 19:08:58

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-05T14:08:52', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '8c072f6a-2861-48e0-9b41-c2c8bd22d963' User entered 'None (1)'	System	05 Sep 2020 19:08:58
	System	05 Sep 2020 19:08:58

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-05T14:08:54', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '8c072f6a-2861-48e0-9b41-c2c8bd22d963' User entered '05 Sep 2020 14:08'	System	05 Sep 2020 19:08:58
	System	05 Sep 2020 19:08:58

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	01 Sep 2020 17:56:37
User entered 'Day 6'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-06T15:24:09', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e155e4f3-53d8-4d46-9b51-ec865dc7f2a7'	System	28 Sep 2020 15:57:00
User entered 'None (1)'	System	28 Sep 2020 15:57:00

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-06T15:24:12', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e155e4f3-53d8-4d46-9b51-ec865dc7f2a7' User entered 'No (N)'	System	28 Sep 2020 15:57:00
	System	28 Sep 2020 15:57:00

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-06T15:24:14', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e155e4f3-53d8-4d46-9b51-ec865dc7f2a7' User entered 'No (N)'	System	28 Sep 2020 15:57:00
	System	28 Sep 2020 15:57:00

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-06T15:24:16', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e155e4f3-53d8-4d46-9b51-ec865dc7f2a7' User entered 'None (1)'	System	28 Sep 2020 15:57:00
	System	28 Sep 2020 15:57:00

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-06T15:24:18', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e155e4f3-53d8-4d46-9b51-ec865dc7f2a7' User entered '06 Sep 2020 15:24'	System	28 Sep 2020 15:57:00
	System	28 Sep 2020 15:57:00

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	01 Sep 2020 17:56:37
User entered 'Day 7'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-07T13:38:12', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'eaefc637-3d88-43c1-878f-60d01d6db222'	System	28 Sep 2020 15:57:08
User entered 'None (1)'	System	28 Sep 2020 15:57:08

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-07T13:38:15', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'eaefc637-3d88-43c1-878f-60d01d6db222' User entered 'No (N)'	System	28 Sep 2020 15:57:08
	System	28 Sep 2020 15:57:08

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-07T13:38:17', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'eaefc637-3d88-43c1-878f-60d01d6db222' User entered 'No (N)'	System	28 Sep 2020 15:57:08
	System	28 Sep 2020 15:57:08

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-07T13:38:19', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'eaefc637-3d88-43c1-878f-60d01d6db222'	System	28 Sep 2020 15:57:08
User entered 'None (1)'	System	28 Sep 2020 15:57:08

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-07T13:38:22', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'eaefc637-3d88-43c1-878f-60d01d6db222' User entered '07 Sep 2020 13:38'	System	28 Sep 2020 15:57:08
	System	28 Sep 2020 15:57:08

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	01 Sep 2020 17:56:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T13:12:07', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '0de2d576-1dec-451a-9a8a-a01bd3aeb88d' User entered 'None (0)'	System	01 Sep 2020 18:12:25
	System	01 Sep 2020 18:12:25

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T13:12:09', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '0de2d576-1dec-451a-9a8a-a01bd3aeb88d' User entered 'None (0)'	System	01 Sep 2020 18:12:25
	System	01 Sep 2020 18:12:25

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T13:12:11', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '0de2d576-1dec-451a-9a8a-a01bd3aeb88d' User entered 'None (0)'	System	01 Sep 2020 18:12:25
	System	01 Sep 2020 18:12:25

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T13:12:13', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '0de2d576-1dec-451a-9a8a-a01bd3aeb88d' User entered 'None (0)'	System	01 Sep 2020 18:12:25
	System	01 Sep 2020 18:12:25

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T13:12:15', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '0de2d576-1dec-451a-9a8a-a01bd3aeb88d' User entered 'None (0)'	System	01 Sep 2020 18:12:25
	System	01 Sep 2020 18:12:25

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T13:12:17', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '0de2d576-1dec-451a-9a8a-a01bd3aeb88d' User entered 'None (0)'	System	01 Sep 2020 18:12:25
	System	01 Sep 2020 18:12:25

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T13:12:20', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '0de2d576-1dec-451a-9a8a-a01bd3aeb88d' User entered 'No (N)'	System	01 Sep 2020 18:12:25
	System	01 Sep 2020 18:12:25

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T13:12:23', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '0de2d576-1dec-451a-9a8a-a01bd3aeb88d' User entered '01 Sep 2020 13:12'	System	01 Sep 2020 18:12:25
	System	01 Sep 2020 18:12:25

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '01 Sep 2020 12:57'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '01 Sep 2020 15:27'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	01 Sep 2020 17:56:37
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T16:45:27', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e3739454-a06f-4933-95a3-9ec6bf29f6f0' User entered 'None (0)'	System	01 Sep 2020 21:45:45
	System	01 Sep 2020 21:45:45

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T16:45:29', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e3739454-a06f-4933-95a3-9ec6bf29f6f0' User entered 'None (0)'	System	01 Sep 2020 21:45:45
	System	01 Sep 2020 21:45:45

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T16:45:31', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e3739454-a06f-4933-95a3-9ec6bf29f6f0' User entered 'None (0)'	System	01 Sep 2020 21:45:45
	System	01 Sep 2020 21:45:45

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T16:45:33', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e3739454-a06f-4933-95a3-9ec6bf29f6f0' User entered 'None (0)'	System	01 Sep 2020 21:45:45
	System	01 Sep 2020 21:45:45

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T16:45:35', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e3739454-a06f-4933-95a3-9ec6bf29f6f0' User entered 'None (0)'	System	01 Sep 2020 21:45:45
	System	01 Sep 2020 21:45:45

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T16:45:37', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e3739454-a06f-4933-95a3-9ec6bf29f6f0' User entered 'None (0)'	System	01 Sep 2020 21:45:45
	System	01 Sep 2020 21:45:45

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T16:45:41', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e3739454-a06f-4933-95a3-9ec6bf29f6f0' User entered 'No (N)'	System	01 Sep 2020 21:45:45
	System	01 Sep 2020 21:45:45

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-01T16:45:43', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e3739454-a06f-4933-95a3-9ec6bf29f6f0' User entered '01 Sep 2020 16:45'	System	01 Sep 2020 21:45:45
	System	01 Sep 2020 21:45:45

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '01 Sep 2020 16:22'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	01 Sep 2020 17:56:37
User entered 'Day 2'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-02T13:11:56', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '39d8a6bc-43f6-4c02-98c7-94435eaab59e'	System	02 Sep 2020 18:12:35
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	02 Sep 2020 18:12:35

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-02T13:12:02', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '39d8a6bc-43f6-4c02-98c7-94435eaab59e'	System	02 Sep 2020 18:12:35
User entered 'Some interference with activity (2)'	System	02 Sep 2020 18:12:35

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-02T13:12:07', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '39d8a6bc-43f6-4c02-98c7-94435eaab59e' User entered 'None (0)'	System	02 Sep 2020 18:12:35
	System	02 Sep 2020 18:12:35

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-02T13:12:10', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '39d8a6bc-43f6-4c02-98c7-94435eaab59e' User entered 'None (0)'	System	02 Sep 2020 18:12:35
	System	02 Sep 2020 18:12:35

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-02T13:12:12', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '39d8a6bc-43f6-4c02-98c7-94435eaab59e' User entered 'None (0)'	System	02 Sep 2020 18:12:35
	System	02 Sep 2020 18:12:35

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-02T13:12:21', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '39d8a6bc-43f6-4c02-98c7-94435eaab59e'	System	02 Sep 2020 18:12:35
User entered 'Some interference with activity not requiring medical attention (2)'	System	02 Sep 2020 18:12:35

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-02T13:12:28', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '39d8a6bc-43f6-4c02-98c7-94435eaab59e' User entered 'No (N)'	System	02 Sep 2020 18:12:35
	System	02 Sep 2020 18:12:35

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-02T13:12:32', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '39d8a6bc-43f6-4c02-98c7-94435eaab59e' User entered '02 Sep 2020 13:12'	System	02 Sep 2020 18:12:35
	System	02 Sep 2020 18:12:35

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	01 Sep 2020 17:56:37
User entered 'Day 3'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-03T12:59:04', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '5b67b3b3-b6bc-432a-ada3-fe143a0d9ad9' User entered 'None (0)'	System	03 Sep 2020 17:59:20
	System	03 Sep 2020 17:59:20

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-03T12:59:06', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '5b67b3b3-b6bc-432a-ada3-fe143a0d9ad9' User entered 'None (0)'	System	03 Sep 2020 17:59:20
	System	03 Sep 2020 17:59:20

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-03T12:59:08', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '5b67b3b3-b6bc-432a-ada3-fe143a0d9ad9' User entered 'None (0)'	System	03 Sep 2020 17:59:20
	System	03 Sep 2020 17:59:20

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-03T12:59:10', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '5b67b3b3-b6bc-432a-ada3-fe143a0d9ad9' User entered 'None (0)'	System	03 Sep 2020 17:59:20
	System	03 Sep 2020 17:59:20

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-03T12:59:11', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '5b67b3b3-b6bc-432a-ada3-fe143a0d9ad9' User entered 'None (0)'	System	03 Sep 2020 17:59:20
	System	03 Sep 2020 17:59:20

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-03T12:59:13', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '5b67b3b3-b6bc-432a-ada3-fe143a0d9ad9' User entered 'None (0)'	System	03 Sep 2020 17:59:20
	System	03 Sep 2020 17:59:20

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-03T12:59:17', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '5b67b3b3-b6bc-432a-ada3-fe143a0d9ad9' User entered 'No (N)'	System	03 Sep 2020 17:59:20
	System	03 Sep 2020 17:59:20

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-03T12:59:19', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '5b67b3b3-b6bc-432a-ada3-fe143a0d9ad9' User entered '03 Sep 2020 12:59'	System	03 Sep 2020 17:59:20
	System	03 Sep 2020 17:59:20

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	01 Sep 2020 17:56:37
User entered 'Day 4'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-04T13:57:42', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '1040ac49-a295-4e3f-b58f-4b3898c5148d' User entered 'None (0)'	System	04 Sep 2020 18:58:03
	System	04 Sep 2020 18:58:03

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-04T13:57:44', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '1040ac49-a295-4e3f-b58f-4b3898c5148d' User entered 'None (0)'	System	04 Sep 2020 18:58:03
	System	04 Sep 2020 18:58:03

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-04T13:57:46', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '1040ac49-a295-4e3f-b58f-4b3898c5148d' User entered 'None (0)'	System	04 Sep 2020 18:58:03
	System	04 Sep 2020 18:58:03

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-04T13:57:49', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '1040ac49-a295-4e3f-b58f-4b3898c5148d' User entered 'None (0)'	System	04 Sep 2020 18:58:03
	System	04 Sep 2020 18:58:03

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-04T13:57:51', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '1040ac49-a295-4e3f-b58f-4b3898c5148d' User entered 'None (0)'	System	04 Sep 2020 18:58:03
	System	04 Sep 2020 18:58:03

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-04T13:57:53', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '1040ac49-a295-4e3f-b58f-4b3898c5148d' User entered 'None (0)'	System	04 Sep 2020 18:58:03
	System	04 Sep 2020 18:58:03

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-04T13:57:58', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '1040ac49-a295-4e3f-b58f-4b3898c5148d' User entered 'No (N)'	System	04 Sep 2020 18:58:03
	System	04 Sep 2020 18:58:03

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-04T13:58:01', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '1040ac49-a295-4e3f-b58f-4b3898c5148d' User entered '04 Sep 2020 13:58'	System	04 Sep 2020 18:58:03
	System	04 Sep 2020 18:58:03

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	01 Sep 2020 17:56:37
User entered 'Day 5'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-05T14:08:58', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '15688abc-e021-45fc-8ed5-b182d342f900' User entered 'None (0)'	System	05 Sep 2020 19:09:16
	System	05 Sep 2020 19:09:16

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-05T14:09:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '15688abc-e021-45fc-8ed5-b182d342f900' User entered 'None (0)'	System	05 Sep 2020 19:09:16
	System	05 Sep 2020 19:09:16

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-05T14:09:02', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '15688abc-e021-45fc-8ed5-b182d342f900' User entered 'None (0)'	System	05 Sep 2020 19:09:16
	System	05 Sep 2020 19:09:16

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-05T14:09:04', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '15688abc-e021-45fc-8ed5-b182d342f900' User entered 'None (0)'	System	05 Sep 2020 19:09:16
	System	05 Sep 2020 19:09:16

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-05T14:09:06', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '15688abc-e021-45fc-8ed5-b182d342f900' User entered 'None (0)'	System	05 Sep 2020 19:09:16
	System	05 Sep 2020 19:09:16

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-05T14:09:08', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '15688abc-e021-45fc-8ed5-b182d342f900' User entered 'None (0)'	System	05 Sep 2020 19:09:16
	System	05 Sep 2020 19:09:16

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-05T14:09:12', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '15688abc-e021-45fc-8ed5-b182d342f900' User entered 'No (N)'	System	05 Sep 2020 19:09:16
	System	05 Sep 2020 19:09:16

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-05T14:09:14', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '15688abc-e021-45fc-8ed5-b182d342f900' User entered '05 Sep 2020 14:09'	System	05 Sep 2020 19:09:16
	System	05 Sep 2020 19:09:16

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	01 Sep 2020 17:56:37
User entered 'Day 6'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-06T15:24:24', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'b2f22c61-02ae-41da-b9a7-f63a4772d683' User entered 'None (0)'	System	28 Sep 2020 15:57:05
	System	28 Sep 2020 15:57:05

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-06T15:24:25', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'b2f22c61-02ae-41da-b9a7-f63a4772d683' User entered 'None (0)'	System	28 Sep 2020 15:57:05
	System	28 Sep 2020 15:57:05

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-06T15:24:27', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'b2f22c61-02ae-41da-b9a7-f63a4772d683' User entered 'None (0)'	System	28 Sep 2020 15:57:05
	System	28 Sep 2020 15:57:05

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-06T15:24:29', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'b2f22c61-02ae-41da-b9a7-f63a4772d683' User entered 'None (0)'	System	28 Sep 2020 15:57:05
	System	28 Sep 2020 15:57:05

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-06T15:24:31', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'b2f22c61-02ae-41da-b9a7-f63a4772d683' User entered 'None (0)'	System	28 Sep 2020 15:57:05
	System	28 Sep 2020 15:57:05

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-06T15:24:33', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'b2f22c61-02ae-41da-b9a7-f63a4772d683' User entered 'None (0)'	System	28 Sep 2020 15:57:05
	System	28 Sep 2020 15:57:05

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-06T15:24:37', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'b2f22c61-02ae-41da-b9a7-f63a4772d683' User entered 'No (N)'	System	28 Sep 2020 15:57:05
	System	28 Sep 2020 15:57:05

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-06T15:24:39', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'b2f22c61-02ae-41da-b9a7-f63a4772d683' User entered '06 Sep 2020 15:24'	System	28 Sep 2020 15:57:05
	System	28 Sep 2020 15:57:05

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	01 Sep 2020 17:56:37
User entered 'Day 7'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-07T13:38:26', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'c8e2b7ff-a8f5-4fa4-8d29-ec8f6db4de8d' User entered 'None (0)'	System	28 Sep 2020 15:57:08
	System	28 Sep 2020 15:57:08

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-07T13:38:28', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'c8e2b7ff-a8f5-4fa4-8d29-ec8f6db4de8d' User entered 'None (0)'	System	28 Sep 2020 15:57:08
	System	28 Sep 2020 15:57:08

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-07T13:38:30', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'c8e2b7ff-a8f5-4fa4-8d29-ec8f6db4de8d' User entered 'None (0)'	System	28 Sep 2020 15:57:08
	System	28 Sep 2020 15:57:08

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-07T13:38:31', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'c8e2b7ff-a8f5-4fa4-8d29-ec8f6db4de8d' User entered 'None (0)'	System	28 Sep 2020 15:57:08
	System	28 Sep 2020 15:57:08

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-07T13:38:33', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'c8e2b7ff-a8f5-4fa4-8d29-ec8f6db4de8d' User entered 'None (0)'	System	28 Sep 2020 15:57:08
	System	28 Sep 2020 15:57:08

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-07T13:38:35', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'c8e2b7ff-a8f5-4fa4-8d29-ec8f6db4de8d' User entered 'None (0)'	System	28 Sep 2020 15:57:08
	System	28 Sep 2020 15:57:08

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-07T13:38:40', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'c8e2b7ff-a8f5-4fa4-8d29-ec8f6db4de8d' User entered 'No (N)'	System	28 Sep 2020 15:57:08
	System	28 Sep 2020 15:57:08

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-09-07T13:38:43', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'c8e2b7ff-a8f5-4fa4-8d29-ec8f6db4de8d' User entered '07 Sep 2020 13:38'	System	28 Sep 2020 15:57:08
	System	28 Sep 2020 15:57:08

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 17:56:37

US3212028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 17:56:37

US3212028

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 13:47:27

US3212028

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '08 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Dec 2020 19:06:07
User entered '8 Sep 2020'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 13:47:27

US3212028

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 13:47:27

US3212028

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty.	Laura Ngansop Djampou (b) (4)	09 Sep 2020 13:47:27

US3212028

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 13:47:41

US3212028

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'I'	System	09 Sep 2020 13:47:41

US3212028

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	16 Sep 2020 14:48:25

US3212028

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '15 Sep 2020'	Laura Ngansop Djampou (b) (4)	16 Sep 2020 14:48:25

US3212028

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	16 Sep 2020 14:48:25

US3212028

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty.	Laura Ngansop Djampou (b) (4)	16 Sep 2020 14:48:25

US3212028

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	16 Sep 2020 14:48:29

US3212028

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'I'	System	16 Sep 2020 14:48:29

US3212028

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	24 Sep 2020 14:43:18

US3212028

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '22 Sep 2020'	Laura Ngansop Djampou (b) (4)	24 Sep 2020 14:43:18

US3212028

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	24 Sep 2020 14:43:18

US3212028

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty.	Laura Ngansop Djampou (b) (4)	24 Sep 2020 14:43:18

US3212028

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	24 Sep 2020 14:43:23

US3212028

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'I'	System	24 Sep 2020 14:43:23

US3212028

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	28 Sep 2020 17:48:49

US3212028

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '28 Sep 2020'	Laura Ngansop Djampou (b) (4)	28 Sep 2020 17:48:49

US3212028

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	28 Sep 2020 17:48:49

US3212028

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'VISIT3'	System	28 Sep 2020 17:48:49

US3212028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	28 Sep 2020 17:49:28

US3212028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '28 Sep 2020'	Laura Ngansop Djampou (b) (4)	28 Sep 2020 17:49:28

US3212028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '10:19'	Laura Ngansop Djampou (b) (4)	28 Sep 2020 17:49:28

US3212028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered '28 Sep 2020 10:19'	System	28 Sep 2020 17:49:28

US3212028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '97.7' F	Laura Ngansop Djampou (b) (4)	28 Sep 2020 17:49:28

US3212028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	28 Sep 2020 17:49:28

US3212028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered empty.	Laura Ngansop Djampou (b) (4)	28 Sep 2020 17:49:28

US3212028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '73'	Laura Ngansop Djampou (b) (4)	28 Sep 2020 17:49:28

US3212028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'bpm'	System	28 Sep 2020 17:49:28

US3212028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '15'	Laura Ngansop Djampou (b) (4)	28 Sep 2020 17:49:28

US3212028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'breaths/min'	System	28 Sep 2020 17:49:28

US3212028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '128'	Laura Ngansop Djampou (b) (4)	28 Sep 2020 17:49:28

US3212028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'mmHg'	System	28 Sep 2020 17:49:28

US3212028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '62'	Laura Ngansop Djampou (b) (4)	28 Sep 2020 17:49:28

US3212028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'mmHg'	System	28 Sep 2020 17:49:28

US3212028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45

US3212028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45

US3212028

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	28 Sep 2020 17:49:39

US3212028

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '28 Sep 2020'	Laura Ngansop Djampou (b) (4)	28 Sep 2020 17:49:39

US3212028

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	28 Sep 2020 17:49:53

US3212028

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '28 Sep 2020'	Laura Ngansop Djampou (b) (4)	28 Sep 2020 17:49:53

US3212028

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '10:44'	Laura Ngansop Djampou (b) (4)	28 Sep 2020 17:49:53

US3212028

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered '28 Sep 2020 10:44'	System	28 Sep 2020 17:49:53

US3212028

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	28 Sep 2020 17:49:58

US3212028

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered '1'	System	28 Sep 2020 17:49:58

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 64'	System	04 Aug 2020 18:08:16

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-10-04T14:23:45', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '53fc5a3c-1980-48d9-8e1c-ace6a25149ae' User entered 'No (N)'	System	04 Oct 2020 19:23:59
	System	04 Oct 2020 19:23:59

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-10-04T14:23:49', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '53fc5a3c-1980-48d9-8e1c-ace6a25149ae'	System	04 Oct 2020 19:23:59
User entered 'No (N)'	System	04 Oct 2020 19:23:59

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-10-04T14:23:55', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '53fc5a3c-1980-48d9-8e1c-ace6a25149ae' User entered '04 Oct 2020 14:23:55'	System	04 Oct 2020 19:23:59
	System	04 Oct 2020 19:23:59

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered '04 Oct 2020 00:01'	System	04 Aug 2020 18:08:16

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered '08 Oct 2020 23:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 71'	System	04 Aug 2020 18:08:16

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-10-11T16:25:16', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'aa7e00e0-7146-4871-9af2-5504617c1900'	System	11 Oct 2020 21:25:27
User entered 'No (N)'	System	11 Oct 2020 21:25:27

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-10-11T16:25:21', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'aa7e00e0-7146-4871-9af2-5504617c1900'	System	11 Oct 2020 21:25:27
User entered 'No (N)'	System	11 Oct 2020 21:25:27

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-10-11T16:25:25', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'aa7e00e0-7146-4871-9af2-5504617c1900' User entered '11 Oct 2020 16:25:25'	System	11 Oct 2020 21:25:27
	System	11 Oct 2020 21:25:27

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered '11 Oct 2020 00:01'	System	04 Aug 2020 18:08:16

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered '15 Oct 2020 23:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 78'	System	04 Aug 2020 18:08:16

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-10-18T13:18:12', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '5b1d4b35-ebde-4b84-b75d-9815076fa8dd' User entered 'No (N)'	System	18 Oct 2020 18:18:24
	System	18 Oct 2020 18:18:24

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-10-18T13:18:17', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '5b1d4b35-ebde-4b84-b75d-9815076fa8dd'	System	18 Oct 2020 18:18:24
User entered 'No (N)'	System	18 Oct 2020 18:18:24

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-10-18T13:18:22', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '5b1d4b35-ebde-4b84-b75d-9815076fa8dd' User entered '18 Oct 2020 13:18:22'	System	18 Oct 2020 18:18:24
	System	18 Oct 2020 18:18:24

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered '18 Oct 2020 00:01'	System	04 Aug 2020 18:08:16

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered '22 Oct 2020 23:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 92'	System	04 Aug 2020 18:08:16

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-11-03T06:14:28', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'b67c2f7d-9f90-4ad7-bd17-ff871d193f26'	System	03 Nov 2020 12:15:22
User entered 'Yes (Y)'	System	03 Nov 2020 12:15:22

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-11-03T06:14:35', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'b67c2f7d-9f90-4ad7-bd17-ff871d193f26'	System	03 Nov 2020 12:15:22
User entered 'No (N)'	System	03 Nov 2020 12:15:22

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-11-03T06:14:39', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'b67c2f7d-9f90-4ad7-bd17-ff871d193f26' User entered 'No (N)'	System	03 Nov 2020 12:15:22
	System	03 Nov 2020 12:15:22

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-11-03T06:14:51', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'b67c2f7d-9f90-4ad7-bd17-ff871d193f26'	System	03 Nov 2020 12:15:22
User entered 'Yes (Y)'	System	03 Nov 2020 12:15:22

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-11-03T06:15:03', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'b67c2f7d-9f90-4ad7-bd17-ff871d193f26'	System	03 Nov 2020 12:15:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Nov 2020 12:15:22

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-11-03T06:15:13', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'b67c2f7d-9f90-4ad7-bd17-ff871d193f26' User entered '03 Nov 2020 06:15:13'	System	03 Nov 2020 12:15:22
	System	03 Nov 2020 12:15:22

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered '01 Nov 2020 00:01'	System	04 Aug 2020 18:08:16

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered '05 Nov 2020 23:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 99'	System	04 Aug 2020 18:08:16

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-11-08T16:03:48', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'ebae5d3a-3586-4c08-a7b3-36611219c6a2' User entered 'No (N)'	System	08 Nov 2020 22:04:02
	System	08 Nov 2020 22:04:02

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-11-08T16:03:53', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'ebae5d3a-3586-4c08-a7b3-36611219c6a2'	System	08 Nov 2020 22:04:02
User entered 'No (N)'	System	08 Nov 2020 22:04:02

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-11-08T16:03:58', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'ebae5d3a-3586-4c08-a7b3-36611219c6a2' User entered '08 Nov 2020 16:03:58'	System	08 Nov 2020 22:04:02
	System	08 Nov 2020 22:04:02

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered '08 Nov 2020 00:01'	System	04 Aug 2020 18:08:16

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered '12 Nov 2020 23:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered 'Day 106'	System	04 Aug 2020 18:08:16

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-11-15T18:01:35', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '4c65d309-ea78-4380-9d7d-346ec10e7755'	System	16 Nov 2020 00:01:45
User entered 'No (N)'	System	16 Nov 2020 00:01:45

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-11-15T18:01:39', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '4c65d309-ea78-4380-9d7d-346ec10e7755'	System	16 Nov 2020 00:01:45
User entered 'No (N)'	System	16 Nov 2020 00:01:45

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-11-15T18:01:43', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '4c65d309-ea78-4380-9d7d-346ec10e7755' User entered '15 Nov 2020 18:01:43'	System	16 Nov 2020 00:01:45
	System	16 Nov 2020 00:01:45

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered '15 Nov 2020 00:01'	System	04 Aug 2020 18:08:16

US3212028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:01:06
Data entry locked.	System	04 Aug 2020 18:08:16
User entered '19 Nov 2020 23:59'	System	04 Aug 2020 18:08:16

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-11-19T17:02:08', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '6d1419bd-fb1c-45f0-820d-7c349987ad53' User entered 'No (N)'	System	19 Nov 2020 23:02:19
	System	19 Nov 2020 23:02:19

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-11-19T17:02:12', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '6d1419bd-fb1c-45f0-820d-7c349987ad53' User entered 'No (N)'	System	19 Nov 2020 23:02:19
	System	19 Nov 2020 23:02:19

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-11-19T17:02:15', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '6d1419bd-fb1c-45f0-820d-7c349987ad53' User entered '19 Nov 2020 17:02:15'	System	19 Nov 2020 23:02:19
	System	19 Nov 2020 23:02:19

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-11-26T18:01:47', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e2e9a2a9-b05d-48c3-aea2-fe04b2187da4'	System	27 Nov 2020 00:01:58
User entered 'No (N)'	System	27 Nov 2020 00:01:58

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Have you been exposed to someone with 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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-11-26T18:01:51', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e2e9a2a9-b05d-48c3-aea2-fe04b2187da4'	System	27 Nov 2020 00:01:58
User entered 'No (N)'	System	27 Nov 2020 00:01:58

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-11-26T18:01:54', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'e2e9a2a9-b05d-48c3-aea2-fe04b2187da4' User entered '26 Nov 2020 18:01:54'	System	27 Nov 2020 00:01:58
	System	27 Nov 2020 00:01:58

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-12-04T10:31:05', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '987617ea-6eac-468b-b445-4863ea2081af' User entered 'No (N)'	System	04 Dec 2020 16:31:15
	System	04 Dec 2020 16:31:15

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Have you been exposed to someone with 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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-12-04T10:31:09', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '987617ea-6eac-468b-b445-4863ea2081af' User entered 'No (N)'	System	04 Dec 2020 16:31:15
	System	04 Dec 2020 16:31:15

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-12-04T10:31:12', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '987617ea-6eac-468b-b445-4863ea2081af' User entered '04 Dec 2020 10:31:12'	System	04 Dec 2020 16:31:15
	System	04 Dec 2020 16:31:15

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-12-10T09:06:52', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'cdfa8608-cbe4-4ef4-99a9-dabc605b4d9b' User entered 'No (N)'	System	10 Dec 2020 15:07:04
	System	10 Dec 2020 15:07:04

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-12-10T09:06:55', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'cdfa8608-cbe4-4ef4-99a9-dabc605b4d9b' User entered 'No (N)'	System	10 Dec 2020 15:07:04
	System	10 Dec 2020 15:07:04

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-12-10T09:07:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'cdfa8608-cbe4-4ef4-99a9-dabc605b4d9b' User entered '10 Dec 2020 09:07:00'	System	10 Dec 2020 15:07:04
	System	10 Dec 2020 15:07:04

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-12-17T20:34:40', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '8e6b211b-766e-4682-b0f4-f90439293017' User entered 'No (N)'	System	18 Dec 2020 02:34:54
	System	18 Dec 2020 02:34:54

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Have you been exposed to someone with 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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-12-17T20:34:44', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '8e6b211b-766e-4682-b0f4-f90439293017' User entered 'No (N)'	System	18 Dec 2020 02:34:54
	System	18 Dec 2020 02:34:54

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-12-17T20:34:47', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '8e6b211b-766e-4682-b0f4-f90439293017' User entered '17 Dec 2020 20:34:47'	System	18 Dec 2020 02:34:54
	System	18 Dec 2020 02:34:54

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-12-24T17:44:15', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'a05e5271-2124-4b7f-98bf-73f7e5df97fb' User entered 'No (N)'	System	24 Dec 2020 23:44:27
	System	24 Dec 2020 23:44:27

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-12-24T17:44:18', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'a05e5271-2124-4b7f-98bf-73f7e5df97fb' User entered 'No (N)'	System	24 Dec 2020 23:44:27
	System	24 Dec 2020 23:44:27

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2020-12-24T17:44:21', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'a05e5271-2124-4b7f-98bf-73f7e5df97fb' User entered '24 Dec 2020 17:44:21'	System	24 Dec 2020 23:44:27
	System	24 Dec 2020 23:44:27

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-01-02T18:18:55', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '0f335d82-4128-4b82-86ee-5bea3d582cfb' User entered 'No (N)'	System	03 Jan 2021 00:19:06
	System	03 Jan 2021 00:19:06

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Have you been exposed to someone with 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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-01-02T18:18:59', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '0f335d82-4128-4b82-86ee-5bea3d582cfb' User entered 'No (N)'	System	03 Jan 2021 00:19:06
	System	03 Jan 2021 00:19:06

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-01-02T18:19:04', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '0f335d82-4128-4b82-86ee-5bea3d582cfb' User entered '02 Jan 2021 18:19:04'	System	03 Jan 2021 00:19:06
	System	03 Jan 2021 00:19:06

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-01-08T10:15:41', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'baa4eed3-37ae-4af7-80ff-f628daf37630'	System	08 Jan 2021 16:15:55
User entered 'No (N)'	System	08 Jan 2021 16:15:55

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Have you been exposed to someone with 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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-01-08T10:15:45', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'baa4eed3-37ae-4af7-80ff-f628daf37630'	System	08 Jan 2021 16:15:55
User entered 'No (N)'	System	08 Jan 2021 16:15:55

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-01-08T10:15:49', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'baa4eed3-37ae-4af7-80ff-f628daf37630' User entered '08 Jan 2021 10:15:49'	System	08 Jan 2021 16:15:55
	System	08 Jan 2021 16:15:55

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-01-15T16:47:37', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'f4490878-9502-43e7-8e8f-8f2f0b326b11' User entered 'No (N)'	System	15 Jan 2021 22:47:49
	System	15 Jan 2021 22:47:49

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Have you been exposed to someone with 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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-01-15T16:47:41', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'f4490878-9502-43e7-8e8f-8f2f0b326b11' User entered 'No (N)'	System	15 Jan 2021 22:47:49
	System	15 Jan 2021 22:47:49

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-01-15T16:47:44', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'f4490878-9502-43e7-8e8f-8f2f0b326b11' User entered '15 Jan 2021 16:47:44'	System	15 Jan 2021 22:47:49
	System	15 Jan 2021 22:47:49

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-01-23T15:59:31', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'eb9f586c-2485-449b-87c3-206daa6d34ae' User entered 'No (N)'	System	23 Jan 2021 21:59:44
	System	23 Jan 2021 21:59:44

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-01-23T15:59:36', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'eb9f586c-2485-449b-87c3-206daa6d34ae'	System	23 Jan 2021 21:59:44
User entered 'No (N)'	System	23 Jan 2021 21:59:44

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-01-23T15:59:41', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'eb9f586c-2485-449b-87c3-206daa6d34ae' User entered '23 Jan 2021 15:59:41'	System	23 Jan 2021 21:59:44
	System	23 Jan 2021 21:59:44

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-02-04T09:45:06', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '70b67d77-2c5b-4455-98e1-d8fe5cca80d3' User entered 'No (N)'	System	04 Feb 2021 15:45:17
	System	04 Feb 2021 15:45:17

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-02-04T09:45:10', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '70b67d77-2c5b-4455-98e1-d8fe5cca80d3' User entered 'No (N)'	System	04 Feb 2021 15:45:17
	System	04 Feb 2021 15:45:17

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-02-04T09:45:14', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '70b67d77-2c5b-4455-98e1-d8fe5cca80d3' User entered '04 Feb 2021 09:45:14'	System	04 Feb 2021 15:45:17
	System	04 Feb 2021 15:45:17

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-02-15T13:48:41', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'd86d385a-833d-4cf7-ab50-e87b63acb798'	System	15 Feb 2021 19:48:50
User entered 'No (N)'	System	15 Feb 2021 19:48:50

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-02-15T13:48:44', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'd86d385a-833d-4cf7-ab50-e87b63acb798'	System	15 Feb 2021 19:48:50
User entered 'No (N)'	System	15 Feb 2021 19:48:50

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-02-15T13:48:48', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'd86d385a-833d-4cf7-ab50-e87b63acb798' User entered '15 Feb 2021 13:48:48'	System	15 Feb 2021 19:48:50
	System	15 Feb 2021 19:48:50

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-02-22T09:57:31', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '74330109-9838-4185-b53a-6955b24d8be0' User entered 'No (N)'	System	22 Feb 2021 15:57:43

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Have you been exposed to someone with 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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-02-22T09:57:35', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '74330109-9838-4185-b53a-6955b24d8be0' User entered 'No (N)'	System	22 Feb 2021 15:57:43

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-02-22T09:57:40', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '74330109-9838-4185-b53a-6955b24d8be0' User entered '22 Feb 2021 09:57:40'	System	22 Feb 2021 15:57:43

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-03-01T09:17:42-06:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '91c82e47-b969-4ab2-8628-81798b7acfab'	System	01 Mar 2021 15:17:55
User entered 'No (N)'	System	01 Mar 2021 15:17:55

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-03-01T09:17:46-06:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '91c82e47-b969-4ab2-8628-81798b7acfab'	System	01 Mar 2021 15:17:55
User entered 'No (N)'	System	01 Mar 2021 15:17:55

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-03-01T09:17:50-06:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '91c82e47-b969-4ab2-8628-81798b7acfab' User entered '01 Mar 2021 09:17:50'	System	01 Mar 2021 15:17:55
	System	01 Mar 2021 15:17:55

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-03-05T13:07:43-06:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'd64a0ee5-1c20-44c2-807a-46a07e6cdf65'	System	05 Mar 2021 19:07:54
User entered 'No (N)'	System	05 Mar 2021 19:07:54

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-03-05T13:07:46-06:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'd64a0ee5-1c20-44c2-807a-46a07e6cdf65'	System	05 Mar 2021 19:07:54
User entered 'No (N)'	System	05 Mar 2021 19:07:54

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-03-05T13:07:50-06:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'd64a0ee5-1c20-44c2-807a-46a07e6cdf65' User entered '05 Mar 2021 13:07:50'	System	05 Mar 2021 19:07:54
	System	05 Mar 2021 19:07:54

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-03-13T07:16:51-06:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '71f92d55-57df-4533-baa1-c3a3b32a2411'	System	13 Mar 2021 13:17:01
User entered 'No (N)'	System	13 Mar 2021 13:17:01

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-03-13T07:16:54-06:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '71f92d55-57df-4533-baa1-c3a3b32a2411'	System	13 Mar 2021 13:17:01
User entered 'No (N)'	System	13 Mar 2021 13:17:01

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-03-13T07:16:58-06:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '71f92d55-57df-4533-baa1-c3a3b32a2411'	System	13 Mar 2021 13:17:01
User entered '13 Mar 2021 07:16:58'	System	13 Mar 2021 13:17:01

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-03-19T19:24:43-05:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '7961117d-1f80-474e-ad99-b53470bd8cf8'	System	20 Mar 2021 00:24:52
User entered 'No (N)'	System	20 Mar 2021 00:24:52

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-03-19T19:24:47-05:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '7961117d-1f80-474e-ad99-b53470bd8cf8'	System	20 Mar 2021 00:24:52
User entered 'No (N)'	System	20 Mar 2021 00:24:52

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-03-19T19:24:50-05:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '7961117d-1f80-474e-ad99-b53470bd8cf8' User entered '19 Mar 2021 19:24:50'	System	20 Mar 2021 00:24:52
	System	20 Mar 2021 00:24:52

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-03-27T17:26:51-05:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '287fad50-ada0-4fe2-a835-d5198acc8b25'	System	27 Mar 2021 22:27:00
User entered 'No (N)'	System	27 Mar 2021 22:27:00

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-03-27T17:26:53-05:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '287fad50-ada0-4fe2-a835-d5198acc8b25'	System	27 Mar 2021 22:27:00
User entered 'No (N)'	System	27 Mar 2021 22:27:00

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-03-27T17:26:57-05:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '287fad50-ada0-4fe2-a835-d5198acc8b25'	System	27 Mar 2021 22:27:00
User entered '27 Mar 2021 17:26:57'	System	27 Mar 2021 22:27:00

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-04-02T16:31:54-05:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'b10e7593-4451-4dbb-bde4-94658c15b1cd' User entered 'No (N)'	System	02 Apr 2021 22:11:19
	System	02 Apr 2021 22:11:19

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-04-02T16:31:56-05:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'b10e7593-4451-4dbb-bde4-94658c15b1cd'	System	02 Apr 2021 22:11:19
User entered 'No (N)'	System	02 Apr 2021 22:11:19

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-04-02T16:31:59-05:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'b10e7593-4451-4dbb-bde4-94658c15b1cd'	System	02 Apr 2021 22:11:19
User entered '02 Apr 2021 16:31:59'	System	02 Apr 2021 22:11:19

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-04-08T12:44:40-05:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '1a04b326-92e0-4d0c-a137-4c929f9d2d17'	System	08 Apr 2021 17:44:50
User entered 'No (N)'	System	08 Apr 2021 17:44:50

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-04-08T12:44:42-05:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '1a04b326-92e0-4d0c-a137-4c929f9d2d17'	System	08 Apr 2021 17:44:50
User entered 'No (N)'	System	08 Apr 2021 17:44:50

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-04-08T12:44:45-05:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '1a04b326-92e0-4d0c-a137-4c929f9d2d17'	System	08 Apr 2021 17:44:50
User entered '08 Apr 2021 12:44:45'	System	08 Apr 2021 17:44:50

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-04-15T12:05:07-05:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '59f1d08a-f523-444d-b1c3-5ecf166a67aa'	System	15 Apr 2021 17:27:02
User entered 'No (N)'	System	15 Apr 2021 17:27:02

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-04-15T12:05:10-05:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '59f1d08a-f523-444d-b1c3-5ecf166a67aa'	System	15 Apr 2021 17:27:02
User entered 'No (N)'	System	15 Apr 2021 17:27:02

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-04-15T12:05:14-05:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '59f1d08a-f523-444d-b1c3-5ecf166a67aa' User entered '15 Apr 2021 12:05:14'	System	15 Apr 2021 17:27:02
	System	15 Apr 2021 17:27:02

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-04-22T17:54:35-05:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'c0c6eb47-eaf3-4386-b507-8cce571dcfdf' User entered 'No (N)'	System	22 Apr 2021 22:54:48

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-04-22T17:54:37-05:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'c0c6eb47-eaf3-4386-b507-8cce571dcfdf'	System	22 Apr 2021 22:54:48
User entered 'No (N)'	System	22 Apr 2021 22:54:48

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-04-22T17:54:41-05:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: 'c0c6eb47-eaf3-4386-b507-8cce571dcfdf'	System	22 Apr 2021 22:54:48
User entered '22 Apr 2021 17:54:41'	System	22 Apr 2021 22:54:48

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-05-01T09:59:36-05:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '070546e4-df1b-413f-b89b-b3cdc71a1481' User entered 'No (N)'	System	01 May 2021 14:59:45
	System	01 May 2021 14:59:45

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-05-01T09:59:38-05:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '070546e4-df1b-413f-b89b-b3cdc71a1481'	System	01 May 2021 14:59:45
User entered 'No (N)'	System	01 May 2021 14:59:45

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-05-01T09:59:42-05:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '070546e4-df1b-413f-b89b-b3cdc71a1481'	System	01 May 2021 14:59:45
User entered '01 May 2021 09:59:42'	System	01 May 2021 14:59:45

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 12:40:29

US3212028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:40:29
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 12:40:29

US3212028

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:45:33

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 07:39:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-03-01T09:17:59-06:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '394b0daa-790a-4487-8536-85d94b737e8d'	System	01 Mar 2021 15:18:11
User entered 'No (N)'	System	01 Mar 2021 15:18:11

US3212028

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:45:33

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:39:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (236DFA53-4661-4044-AC0C-1F872D7F263C)', Time: '2021-03-01T09:18:03-06:00', User OID: 'PatientReportedOutcome (US3212028)', ODM File OID: '394b0daa-790a-4487-8536-85d94b737e8d' User entered '01 Mar 2021 09:18:03'	System	01 Mar 2021 15:18:11
	System	01 Mar 2021 15:18:11

US3212028

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 14:14:18

US3212028

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered '26 Oct 2020'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 14:14:18

US3212028

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Contact Not Made (CONTACT NOT MADE)'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 14:14:18

US3212028

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Attempted day 85 safety call. No answer'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 14:14:18

US3212028

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:51:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	27 Oct 2020 14:14:05

US3212028

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:56:45
User entered 'I'	System	27 Oct 2020 14:14:05

US3212028

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	03 Dec 2020 18:35:27

US3212028

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered '02 Dec 2020'	Laura Ngansop Djampou (b) (4)	03 Dec 2020 18:35:27

US3212028

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	03 Dec 2020 18:35:27

US3212028

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered empty.	Laura Ngansop Djampou (b) (4)	03 Dec 2020 18:35:27

US3212028

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	03 Dec 2020 18:35:35

US3212028

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User entered 'I'	System	03 Dec 2020 18:35:35

US3212028

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	30 Dec 2020 15:11:51

US3212028

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered '29 Dec 2020'	Laura Ngansop Djampou (b) (4)	30 Dec 2020 15:11:51

US3212028

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	30 Dec 2020 15:11:51

US3212028

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered empty.	Laura Ngansop Djampou (b) (4)	30 Dec 2020 15:11:51

US3212028

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	30 Dec 2020 15:11:55

US3212028

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User entered 'I'	System	30 Dec 2020 15:11:55

US3212028

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	09 Feb 2021 16:13:46

US3212028

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered '29 Jan 2021'	Laura Ngansop Djampou (b) (4)	09 Feb 2021 16:13:46

US3212028

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	09 Feb 2021 16:13:46

US3212028

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered empty.	Laura Ngansop Djampou (b) (4)	09 Feb 2021 16:13:46

US3212028

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	09 Feb 2021 16:13:28

US3212028

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User entered 'I'	System	09 Feb 2021 16:13:28

US3212028

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	26 Feb 2021 14:36:02

US3212028

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered '24 Feb 2021'	Laura Ngansop Djampou (b) (4)	26 Feb 2021 14:36:02

US3212028

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[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 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	26 Feb 2021 14:36:02

US3212028

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User entered 'VISIT4'	System	26 Feb 2021 14:36:02

US3212028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 16:43:00

US3212028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered '24 Feb 2021'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 16:43:00

US3212028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered '12:11'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 16:43:00

US3212028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User entered '24 Feb 2021 12:11'	System	30 Mar 2021 16:43:00

US3212028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered '97.3' F	Laura Ngansop Djampou (b) (4)	30 Mar 2021 16:43:00

US3212028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 16:43:00

US3212028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered empty.	Laura Ngansop Djampou (b) (4)	30 Mar 2021 16:43:00

US3212028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered '62'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 16:43:00

US3212028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User entered 'bpm'	System	30 Mar 2021 16:43:00

US3212028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered '15'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 16:43:00

US3212028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User entered 'breaths/min'	System	30 Mar 2021 16:43:00

US3212028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered '138'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 16:43:00

US3212028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User entered 'mmHg'	System	30 Mar 2021 16:43:00

US3212028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered '80'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 16:43:00

US3212028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User entered 'mmHg'	System	30 Mar 2021 16:43:00

US3212028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29

US3212028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29

US3212028

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	26 Feb 2021 14:35:52

US3212028

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered '24 Feb 2021'	Laura Ngansop Djampou (b) (4)	26 Feb 2021 14:35:52

US3212028

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 16:17:16

US3212028

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered '24 Feb 2021'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 16:17:16

US3212028

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered '12:40'	Laura Ngansop Djampou (b) (4)	01 Mar 2021 16:17:16

US3212028

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User entered '24 Feb 2021 12:40'	System	01 Mar 2021 16:17:16

US3212028

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	26 Feb 2021 14:35:40

US3212028

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:29
User entered 'I'	System	26 Feb 2021 14:35:40

US3212028

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:44
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 14:46:20

US3212028

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:44
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered '29 Mar 2021'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 14:46:20

US3212028

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:44
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 14:46:20

US3212028

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:44
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered empty.	Laura Ngansop Djampou (b) (4)	30 Mar 2021 14:46:20

US3212028

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:44
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	30 Mar 2021 14:45:58

US3212028

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:44
User entered 'I'	System	30 Mar 2021 14:45:58

US3212028

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	30 Apr 2021 18:12:49
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	29 Apr 2021 16:40:04

US3212028

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	30 Apr 2021 18:12:49
User entered '27 Apr 2021'	Laura Ngansop Djampou (b) (4)	29 Apr 2021 16:40:04

US3212028

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	30 Apr 2021 18:12:49
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	29 Apr 2021 16:40:04

US3212028

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	30 Apr 2021 18:12:49
User entered empty.	Laura Ngansop Djampou (b) (4)	29 Apr 2021 16:40:04

US3212028

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	30 Apr 2021 18:12:49
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	29 Apr 2021 16:40:10

US3212028

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 16:40:10

US3212028

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

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:53
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered 'Yes (Y)'	Heather Leary (b) (4)	15 Jan 2021 21:19:12

US3212028

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

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:53
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered '15 Jan 2021'	Heather Leary (b) (4)	15 Jan 2021 21:19:12

US3212028

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

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

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 12:52:53
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered 'Clinic (Clinic)'	Heather Leary (b) (4)	15 Jan 2021 21:19:12

US3212028

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

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:53
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 21:19:12

US3212028

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

Form: Unblinding

Generated On: 09 Jun 2021 15:45:33

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:53
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered '15 Jan 2021'	Heather Leary (b) (4)	15 Jan 2021 21:19:30

US3212028

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

Form: Unblinding

Generated On: 09 Jun 2021 15:45:33

[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 12:52:53
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:23:55
User entered '0'	Heather Leary (b) (4)	22 Apr 2021 14:18:19
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:19:30

US3212028

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

Form: Unblinding

Generated On: 09 Jun 2021 15:45:33

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:53
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered 'Yes (Y)'	Heather Leary (b) (4)	15 Jan 2021 21:19:30

US3212028

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

Form: Unblinding

Generated On: 09 Jun 2021 15:45:33

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:53
User closed query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 14:28:32
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:23:55
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 14:18:43
User entered 'Amendment 6 or later (Amendment 6 or later)'	Heather Leary (b) (4)	22 Apr 2021 14:18:19
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 05:33:40
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:19:30

US3212028

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

Form: Unblinding

Generated On: 09 Jun 2021 15:45:33

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:53
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered '15 Jan 2021'	Heather Leary (b) (4)	15 Jan 2021 21:19:30

US3212028

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

Form: Unblinding

Generated On: 09 Jun 2021 15:45:33

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:53
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered 'mRNA-1273 (mRNA-1273)'	Heather Leary (b) (4)	15 Jan 2021 21:19:30

US3212028

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

Form: Unblinding

Generated On: 09 Jun 2021 15:45:33

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:53
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 01:10:11
User entered 'mRNA-1273 (mRNA-1273)'	Heather Leary (b) (4)	15 Jan 2021 21:19:30

US3212028

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

Form: Unblinding

Generated On: 09 Jun 2021 15:45:33

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:53
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 01:10:11
User entered 'mRNA-1273 (mRNA-1273)'	Heather Leary (b) (4)	15 Jan 2021 21:19:30

US3212028

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

Form: Unblinding

Generated On: 09 Jun 2021 15:45:33

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:53
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered 'No (N)'	Heather Leary (b) (4)	15 Jan 2021 21:19:30

US3212028

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

Form: Unblinding

Generated On: 09 Jun 2021 15:45:33

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:53
User entered empty.	System	15 Jan 2021 21:19:30

US3212028

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

Form: Unblinding

Generated On: 09 Jun 2021 15:45:33

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:53
User entered empty.	System	15 Jan 2021 21:19:30

US3212028

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:53
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered 'Yes (Y)'	Heather Leary (b) (4)	15 Jan 2021 21:19:50

US3212028

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:53
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered '15 Jan 2021'	Heather Leary (b) (4)	15 Jan 2021 21:19:50

US3212028

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:53
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
User entered '10:50'	Heather Leary (b) (4)	15 Jan 2021 21:19:50

US3212028

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:53
User entered '15 Jan 2021 10:50'	System	15 Jan 2021 21:19:50

US3212028

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:45:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:53
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered 'Yes (Y)'	Heather Leary (b) (4)	15 Jan 2021 21:20:02

US3212028

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:45:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:53
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered '15 Jan 2021'	Heather Leary (b) (4)	15 Jan 2021 21:20:02

US3212028

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:45:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:53
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered '10:48'	Heather Leary (b) (4)	15 Jan 2021 21:20:02

US3212028

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:53
User entered '15 Jan 2021 10:48'	System	15 Jan 2021 21:20:02

US3212028

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:45:33

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:27:53
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User closed query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 92, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 08:39:33
Query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 92, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'all data is entered for this subject' (Site from DM).	Reagan Reed (b) (4)	22 Mar 2021 14:20:23
User opened query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 92, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 14:39:24
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:48:08
User entered 'Yes (Y)' reason for change: New Information	Heather Leary (b) (4)	28 Oct 2020 15:37:38
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 14:04:48

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:47:35
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:06
User entered 'USA-US115-2020-mRNA-1273-P301000007'	System	29 Oct 2020 13:23:01
User entered 'New'	(b) (4), (b) (6)	29 Oct 2020 13:23:01

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute coronary syndrome, LLT: Non ST segment elevation acute coronary syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 12:15:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 12:15:34
Data point term sent to Coder	System	23 Nov 2020 22:09:21
Coding entries removed.	Reagan Reed (b) (4)	23 Nov 2020 22:08:59
	(b) (4)	
User entered 'acute coronary syndrome (non ST Elevated Myocardial Infarction)' reason for change: Data Entry Error	Reagan Reed (b) (4)	23 Nov 2020 22:08:59
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute myocardial infarction, LLT: Non ST segment elevation myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 18:46:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 18:46:49
Data point term sent to Coder	System	18 Nov 2020 14:19:54
DataPoint Un-verified.	Afifah Ayub (b) (4)	18 Nov 2020 14:19:03
	(b) (4)	
Coding entries removed.	Afifah Ayub (b) (4)	18 Nov 2020 14:19:03
	(b) (4)	
User entered 'non ST Elevated Myocardial Infarction' reason for change: Data Entry Error	Afifah Ayub (b) (4)	18 Nov 2020 14:19:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:47:37
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 18:06:20
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 18:06:20
Data point term sent to Coder	System	28 Oct 2020 15:40:08
User entered 'coronary artery disease'	Heather Leary (b) (4)	28 Oct 2020 15:39:33
	(b) (4)	

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:47:40
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:47:43
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:47:45
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:47:47
User entered '20 Oct 2020'	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:54:35
User closed query 'Per source, start time of AE is 17:30. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 12:54:29
Query 'Per source, start time of AE is 17:30. Please verify with source and update EDC accordingly.' answered with 'per guidelines we are not to capture times in EDC unless within 24 hours of study injection' (Site from CRA).	Reagan Reed (b) (4) (b) (4)	09 Nov 2020 16:57:32
User opened query 'Per source, start time of AE is 17:30. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 16:48:13
User closed query 'Start time is present for an AE thatSystem did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).		28 Oct 2020 15:40:07
User entered empty; reason for change Data Entry Error	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:40:07
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	28 Oct 2020 15:39:33
User entered '17:30'	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 15:40:07
User entered '20 Oct 2020 17:30'	System	28 Oct 2020 15:39:33

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). DataPoint Un-verified.	System Reagan Reed (b) (4) (b) (4)	04 Dec 2020 21:50:03 04 Dec 2020 21:50:03
User entered 'No (N)' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 21:50:03
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). DataPoint Verified.	System (b) (4), (b) (6)	04 Dec 2020 21:49:49 09 Nov 2020 16:48:17
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
	(b) (4)	
User closed query 'Per CDM: 'Outcome' = Recovering/Resolving but 'End Date' (20-OCT-2020) is recorded? Please review and update accordingly, else clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 21:30:00
Query 'Per CDM: 'Outcome' = Recovering/Resolving but 'End Date' (20-OCT-2020) is recorded? Please review and update accordingly, else clarify. ' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	09 Dec 2020 17:14:41
User opened query 'Per CDM: 'Outcome' = Recovering/Resolving but 'End Date' (20-OCT-2020) is recorded? Please review and update accordingly, else clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 05:54:15
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	08 Dec 2020 05:53:50
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 16:24:27
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'updated' (Site from System).	Reagan Reed (b) (4)	04 Dec 2020 21:51:01
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'updated' (Site from Safety).	Reagan Reed (b) (4)	04 Dec 2020 21:50:54
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	04 Dec 2020 21:49:49
DataPoint Un-verified.	Reagan Reed (b) (4)	04 Dec 2020 21:49:49
User entered '20 Oct 2020' reason for change: Data Entry Error	Reagan Reed (b) (4)	04 Dec 2020 21:49:49

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:20:35
	(b) (4), (b) (6)	09 Nov 2020 16:48:19
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 14:41:54
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'coronary artery disease does not heal or resolve this is a new diagnosis that will remain in his medical history for the rest of his life. This event will never be recovered resolved.' (Site from Safety).	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 16:45:25
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 14:26:47
User entered empty.	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:48:21
User entered empty.	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 15:39:33

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:48:28
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:57:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:48:37
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:48:48
User entered '0'	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:48:50
User entered '0'	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:48:52
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 14:41:36
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject is currently still hospitalized for recovery' (Site from System).	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:40:35
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	28 Oct 2020 15:39:33
User entered 'I'	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	((b) (4), (b) (6)	09 Nov 2020 16:50:27
User entered '23 Oct 2020'	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User closed query 'Per CDM: Response noted 'Subject is currently still hospitalized for recovery'. Please update 'Hospital Discharge Date' once data becomes known. Thanks' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 08:49:59
Query 'Per CDM: Response noted 'Subject is currently still hospitalized for recovery'. Please update 'Hospital Discharge Date' once data becomes known. Thanks' answered with 'updated' (Site from DM).	(b) (4), (b) (6) Reagan Reed (b) (4) (b) (4)	09 Nov 2020 16:49:48 06 Nov 2020 16:57:08
User entered '29 Oct 2020' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 16:56:31
User opened query 'Per CDM: Response noted 'Subject is currently still hospitalized for recovery'. Please update 'Hospital Discharge Date' once data becomes known. Thanks' (Site from DM). User entered empty.	(b) (4), (b) (6) Heather Leary (b) (4) (b) (4)	05 Nov 2020 14:45:44 28 Oct 2020 15:39:33

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:54:39
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:54:41
User entered empty.	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:54:46
User entered '0'	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:54:48
User entered '0'	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:54:50
User entered '0'	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:54:57
User entered 'Not Related (NOT RELATED)'	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:55:00
User entered 'Not Related (NOT RELATED)'	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

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Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:55:05
User closed query 'PV Query: As the last dose of was given on 01 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 14:42:00
Query 'PV Query: As the last dose of was given on 01 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 16:46:50
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 16:45:48
User opened query 'PV Query: As the last dose of was given on 01 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 14:26:35
User entered 'None (NONE)'	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

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Folder: Adverse Events

Form: Adverse Events (1)

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None

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:55:15
User entered '0'	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:55:16
User entered 'I'	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 15:07:17
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'please see procedure log ' (Site from DM).	Reagan Reed (b) (4) (b) (4)	23 Nov 2020 22:10:11
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 09:37:31
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:55:18
User entered 'I'	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	09 Dec 2020 17:14:35
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 16:24:33
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated per investigator' (Site from Safety).	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 21:54:00
DataPoint Un-verified.	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 21:50:38
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 21:50:38
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:20:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:55:20
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 14:42:08
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'again, Coronary Artery Disease is not something you ever recover from. this is a life long diagnosis. this is not an isolated event.' (Site from Safety).	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 16:47:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 14:26:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Heather Leary (b) (4)	28 Oct 2020 15:39:33

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Folder: Adverse Events

Form: Adverse Events (1)

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

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:55:26
User entered empty.	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:39:33

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User closed query 'PV Query: Thank you for your response. Documents not received. Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342. Please keep query open until information is received. ' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 16:24:46
User closed query 'PV Query: Thank you for your response. Please keep query open until signs, symptoms and circumstances surrounding the event are provided. ' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 16:24:43
User closed query 'PV Query: Thank you for your response. Please keep query open until results of any COVID-19 testing is provided. Testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 16:24:40
User closed query 'PV Query: Thank you for your response. Please keep query open until relevant laboratory and diagnostic test results are provided. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 16:24:36
Query 'PV Query: Thank you for your response. Please keep query open until signs, symptoms and circumstances surrounding the event are provided. ' answered with 'provided' (Site from Safety).	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 21:52:55
Query 'PV Query: Thank you for your response. Please keep query open until results of any COVID-19 testing is provided. Testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'updated see narrative ' (Site from Safety).	Reagan Reed (b) (4) (b) (4)	04 Dec 2020 21:52:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Narrative](#)

Audit	User	Time (GMT)
User entered 'CORONARY ARTERY DISEASE REQUIRING CORONARY ARTERY BYPASS GRAFT X 2 VESSELS. SUBJECT TESTED NEGATIVE FOR COVID19 IN HOSPITAL on 20OCT2020.' reason for change: Data Entry Error	Reagan Reed (b) (4)	04 Dec 2020 21:52:36
User entered 'CORONARY ARTERY DISEASE REQUIRING CORONARY ARTERY BYPASS GRAFT X 2 VESSELS. Subject tested negative for covid19 in hospital.' reason for change: Data Entry Error	Reagan Reed (b) (4)	04 Dec 2020 21:51:55
Query 'PV Query: Thank you for your response. Please keep query open until relevant laboratory and diagnostic test results are provided. Please include units and reference ranges if applicable. ' answered with 'Discharge summary provided 04DEC2020 ' (Site from Safety).	Reagan Reed (b) (4)	04 Dec 2020 21:51:31
DataPoint Un-verified.	Reagan Reed (b) (4)	04 Dec 2020 21:49:23
User entered 'Coronary artery disease requiring coronary artery bypass graft x 2 vessels' reason for change: Data Entry Error	Reagan Reed (b) (4)	04 Dec 2020 21:49:23
Query 'PV Query: Thank you for your response. Documents not received. Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342. Please keep query open until information is received. ' answered with 'sent 04DEC2020' (Site from Safety).	Reagan Reed (b) (4)	04 Dec 2020 21:48:23
Query 'PV Query: Thank you for your response. Please keep query open until treatment medications are provided. Please provide any additional 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. ' canceled (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 16:19:05

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Thank you for your response. Documents not received. Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342. Please keep query open until information is received. ' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:22:38
User opened query 'PV Query: Thank you for your response. Please keep query open until signs, symptoms and circumstances surrounding the event are provided. ' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:22:15
User opened query 'PV Query: Thank you for your response. Please keep query open until results of any COVID-19 testing is provided. Testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:21:56
User opened query 'PV Query: Thank you for your response. Please keep query open until relevant laboratory and diagnostic test results are provided. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:21:28
User opened query 'PV Query: Thank you for your response. Please keep query open until treatment medications are provided. Please provide any additional 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)	16 Nov 2020 16:21:02
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:56:31
User closed query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 14:42:52

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide signs, symptoms and circumstances surrounding the event.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 14:42:27
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 14:42:24
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 14:42:17
User closed query 'PV Query: Please provide any additional 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 Nov 2020 14:42:12
Query 'PV Query: Please provide signs, symptoms and circumstances surrounding the event.' answered with 'waiting on medical records, will update the sponsor when we receive medical records. We have requested medical records on 28OCT2020 and 06NOV2020. Still no records received. ' (Site from Safety).	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 16:50:14
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'waiting on medical records, will update the sponsor when we receive medical records. We have requested medical records on 28OCT2020 and 06NOV2020. Still no records received. ' (Site from Safety).	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 16:50:00

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any additional 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 'waiting on medical records, will update the sponsor when we receive medical records. We have requested medical records on 28OCT2020 and 06NOV2020. Still no records received. ' (Site from Safety).	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 16:49:44
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'waiting on medical records, will update the sponsor when we receive medical records. We have requested medical records on 28OCT2020 and 06NOV2020. Still no records received. ' (Site from Safety).	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 16:49:38
Query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' answered with 'waiting on medical records, will update the sponsor when we receive medical records. We have requested medical records on 28OCT2020 and 06NOV2020. Still no records received. ' (Site from Safety).	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 16:48:46
User opened query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Nov 2020 14:27:23
User opened query 'PV Query: Please provide signs, symptoms and circumstances surrounding the event.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Nov 2020 14:27:16
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Nov 2020 14:27:10

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Folder: Adverse Events

Form: Adverse Events (1)

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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.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 14:27:03
User opened query 'PV Query: Please provide any additional 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)	06 Nov 2020 14:26:57
User entered 'Coronary artery disease requiring coronary artery bypass graft. Currently hospitalized for postoperative recovery'	Heather Leary (b) (4)	28 Oct 2020 15:39:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Oct 2020 15:39:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 15:39:33

US3212028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Oct 2020 15:39:33

US3212028

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:32:27
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) (b) (4)	04 Nov 2020 18:30:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 18:30:26
Data point term sent to Coder	System	04 Nov 2020 18:14:32
User entered 'Gastroesophageal reflux disease'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:32:41
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:32:54
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:34:00
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

US3212028

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:33:42
User entered '28 Oct 2020'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:57:00
User closed query 'Per source, the start time is 00:01. Please confirm whether start time is accurate in source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 12:56:56
Query 'Per source, the start time is 00:01. Please confirm whether start time is accurate in source and update EDC accordingly.' answered with 'time not necessary per protocol ' (Site from CRA).	Reagan Reed (b) (4) (b) (4)	09 Nov 2020 16:29:33
User opened query 'Per source, the start time is 00:01. Please confirm whether start time is accurate in source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 15:34:51
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 18:13:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:35:07
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:35:09
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:35:11
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 18:13:48

US3212028

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:35:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

US3212028

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:35:16
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

US3212028

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:35:39
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

US3212028

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:35:41
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

US3212028

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:35:42
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

US3212028

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:35:46
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

US3212028

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:35:47
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

US3212028

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:35:49
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

US3212028

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:35:50
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

US3212028

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:35:52
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

US3212028

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:35:54
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

US3212028

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:35:55
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

US3212028

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:36:03
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

US3212028

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:36:08
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

US3212028

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:36:11
User entered 'None (NONE)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

US3212028

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

None

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:36:15
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

US3212028

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:36:16
User entered 'I'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

US3212028

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:36:18
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

US3212028

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:36:20
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

US3212028

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:36:22
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

US3212028

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:36:24
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:13:48

US3212028

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Nov 2020 18:13:48

US3212028

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Nov 2020 18:13:48

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:38:20
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 18:45:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 18:45:29
Data point term sent to Coder	System	04 Nov 2020 18:14:32
User entered 'Worsening of hypertension'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:38:23
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:38:25
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:38:27
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:38:31
User entered '29 Oct 2020'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User closed query 'Per source, start time of AE is 06:00. Please confirm with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 12:57:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:57:08
Query 'Per source, start time of AE is 06:00. Please confirm with source and update EDC accordingly.' answered with 'time not necessary per protocol ' (Site from CRA).	Reagan Reed (b) (4) (b) (4)	09 Nov 2020 16:32:15
User opened query 'Per source, start time of AE is 06:00. Please confirm with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 15:39:04
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:42:11
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:42:12
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:42:14
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:42:16
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:42:18
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:43:02
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:43:05
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:43:07
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:43:09
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:43:11
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:43:13
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:43:14
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:43:16
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:43:18
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:43:20
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:43:22
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:43:23
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:43:25
User entered 'None (NONE)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

None

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:43:48
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:43:50
User entered 'I'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:43:52
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:43:54
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:43:56
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:43:58
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Nov 2020 18:14:27

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:44:12
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 18:16:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 18:16:26
Data point term sent to Coder	System	04 Nov 2020 18:15:40
User entered 'Worsening of hypercholesterolemia'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:44:14
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:44:22
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:44:23
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:44:26
User entered '29 Oct 2020'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User closed query 'Per source, AE start time is 09:00. Please confirm with source and update EDC accordingly.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 12:57:24 10 Nov 2020 12:57:19
Query 'Per source, AE start time is 09:00. Please confirm with source and update EDC accordingly.' answered with 'start time not necessary per protocol ' (Site from CRA). User opened query 'Per source, AE start time is 09:00. Please confirm with source and update EDC accordingly.' (Site from CRA). User entered empty.	Reagan Reed (b) (4) (b) (4) (b) (4), (b) (6) Afifah Ayub (b) (4) (b) (4)	09 Nov 2020 16:32:50 09 Nov 2020 15:45:02 04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:45:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:45:12
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:45:14
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:45:19
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:45:21
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:45:58
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:45:59
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:46:01
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:46:38
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:46:39
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:46:48
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:46:50
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:46:53
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:46:56
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:46:57
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:45:55
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:45:53
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:02:41
User closed query 'Per source, action take with IP is "Not Applicable" rather than "None". Please review source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 17:02:39
Query 'Per source, action take with IP is "Not Applicable" rather than "None". Please review source and update EDC accordingly.' answered with 'corrected per source' (Site from CRA).	Reagan Reed (b) (4) (b) (4)	09 Nov 2020 16:54:36
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	09 Nov 2020 16:53:25
User opened query 'Per source, action take with IP is "Not Applicable" rather than "None". Please review source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 15:47:39
User entered 'None (NONE)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

None

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:47:43
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:47:45
User entered 'I'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:47:47
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:47:49
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:47:50
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:47:52
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:45:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Nov 2020 18:15:36

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User closed query 'Per CDM: Response noted ' general pain post-op'. Please review/update AE accordingly as per the previous query. Thank you ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 08:53:12
Query 'Per CDM: Response noted ' general pain post-op'. Please review/update AE accordingly as per the previous query. Thank you ' answered with 'Procedure associated with this AE is coronary artery bypass graft. Pain associated with this procedure can be localized to the chest wall AND generalized pain in the upper back and shoulders as well as the site from which the vein was dissected for the bypass. Post operative pain is a sufficient term to describe acute post operative pain of any location and is coded G89.18 in the ICD 10. ' (Site from DM).	Heather Leary (b) (4)	26 Jan 2021 17:59:05
User opened query 'Per CDM: Response noted ' general pain post-op'. Please review/update AE accordingly as per the previous query. Thank you ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 11:39:55
User closed query 'Per DM CLR: Please review and update AE term to reflect specific body location of POST OPERATIVE PAIN. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 11:39:55
Query 'Per DM CLR: Please review and update AE term to reflect specific body location of POST OPERATIVE PAIN. Please reconcile with the ConMed eCRF so there is an appropriate match. ' answered with 'this is general pain post-op as post operative pain can be both at surgical site and beyond. ' (Site from DM).	Reagan Reed (b) (4)	25 Jan 2021 14:25:48
User opened query 'Per DM CLR: Please review and update AE term to reflect specific body location of POST OPERATIVE PAIN. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	24 Jan 2021 07:25:53

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Postoperative pain - version MedDRA\\23.0.	Coder Import (b) (4)	13 Jan 2021 20:53:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Jan 2021 20:53:04
Data point term sent to Coder	System	13 Jan 2021 20:52:29
User entered 'POST OPERATIVE PAIN'	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered '23 Oct 2020'	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	13 Jan 2021 20:52:15
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:52:15
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	13 Jan 2021 20:51:47
User entered '12:00'	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User entered empty.	System	13 Jan 2021 20:52:15
User entered '23 Oct 2020 12:00'	System	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 20:52:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Jan 2021 20:52:15
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:52:15
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 20:51:47
User entered empty.	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered '11 Nov 2020'	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:52:15
User entered '12:00'	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User entered empty.	System	13 Jan 2021 20:52:15
User entered '11 Nov 2020 12:00'	System	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Jan 2021 14:20:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Jan 2021 14:20:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Heather Leary (b) (4)	14 Jan 2021 14:20:43
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 20:51:47
User entered empty.	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered '0'	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered '0'	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered '0'	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered '0'	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered '0'	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered '0'	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Jan 2021 14:20:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Jan 2021 14:20:43
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Heather Leary (b) (4)	14 Jan 2021 14:20:43
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 20:51:47
User entered empty.	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Jan 2021 14:20:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Jan 2021 14:20:43
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Heather Leary (b) (4)	14 Jan 2021 14:20:43
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 20:51:47
User entered empty.	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Jan 2021 14:20:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Jan 2021 14:20:43
User entered 'None (NONE)' reason for change: Data Entry Error	Heather Leary (b) (4)	14 Jan 2021 14:20:43
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 20:51:47
User entered empty.	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered '0'	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered 'I'	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered '0'	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Laura Ngansop Djampou (b) (4)	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User entered '0'	System	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11
User entered '1'	System	13 Jan 2021 20:51:47

US3212028

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:45:33

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:17:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:45:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:27:53
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User closed query 'Per ETRTR: According to SAE "Coronary Artery Disease" page, medication was dosed for SAE. Please add Medication dosing details for SAE "Coronary Artery Disease " within ConMeds page, thanks.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 16:41:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:48:52
Query 'Per ETRTR: According to SAE "Coronary Artery Disease" page, medication was dosed for SAE. Please add Medication dosing details for SAE "Coronary Artery Disease " within ConMeds page, thanks.' answered with 'Medication has been added under ConMeds' (Site from CRA).	Nirja Shah (b) (4)	04 Nov 2020 21:49:32
User opened query 'Per ETRTR: According to SAE "Coronary Artery Disease" page, medication was dosed for SAE. Please add Medication dosing details for SAE "Coronary Artery Disease " within ConMeds page, thanks.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 16:34:50
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Aug 2020 17:45:48

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:20
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:50:12
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)	04 Aug 2020 17:48:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	04 Aug 2020 17:48:09
Data point term sent to Coder User entered 'Atorvastatin'	System Afifah Ayub (b) (4)	04 Aug 2020 17:47:07 04 Aug 2020 17:47:03

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:20
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:50:15
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Aug 2020 17:47:03

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:20
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:50:17
User entered 'hypercholesterolemia'	Afifah Ayub (b) (4)	04 Aug 2020 17:47:03

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:20
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User closed query 'Per source, Atorvastatin with the 00-000-2000 start date was dosed at 10 mg. Please update dosing in EDC in accordance with this start date.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 12:55:10
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:06
Query 'Per source, Atorvastatin with the 00-000-2000 start date was dosed at 10 mg. Please update dosing in EDC in accordance with this start date.' answered with 'updated' (Site from CRA).	Heather Leary (b) (4)	09 Nov 2020 17:06:24
User entered '10' reason for change: Data Entry Error	(b) (4)	09 Nov 2020 17:06:18
User opened query 'Per source, Atorvastatin with the 00-000-2000 start date was dosed at 10 mg. Please update dosing in EDC in accordance with this start date.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 15:55:46
User entered '80' reason for change: Data Entry Error	Afifah Ayub (b) (4)	04 Nov 2020 18:09:03
User entered '10'	Afifah Ayub (b) (4)	04 Aug 2020 17:47:03

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:20
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:00:50
User entered 'mg (mg)'	Afifah Ayub (b) (4)	04 Aug 2020 17:47:03

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:20
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:00:51
User entered empty.	Afifah Ayub (b) (4)	04 Aug 2020 17:47:03

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:20
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:01:03
User entered 'once daily (QD)'	Afifah Ayub (b) (4)	04 Aug 2020 17:47:03

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:20
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:01:04
User entered empty.	Afifah Ayub (b) (4)	04 Aug 2020 17:47:03

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:20
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:01:08
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4)	04 Aug 2020 17:47:03

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:20
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:01:10
User entered empty.	Afifah Ayub (b) (4)	04 Aug 2020 17:47:03

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:20
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:01:15
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)	06 Aug 2020 12:40:14
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)	04 Aug 2020 21:04:51
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	04 Aug 2020 18:08:16
User entered 'UN UNK 2000'	Afifah Ayub (b) (4)	04 Aug 2020 17:47:03

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:20
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:01:17
User entered '0'	Afifah Ayub (b) (4)	04 Aug 2020 17:47:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:20
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User closed query 'Please update to include a stop date as dosing was changed due to AE. Create a stop date for the 10 mg dosing and a new ConMed line for the 80 mg as ongoing.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 12:55:29
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:55:26
Query 'Please update to include a stop date as dosing was changed due to AE. Create a stop date for the 10 mg dosing and a new ConMed line for the 80 mg as ongoing.' answered with 'updated' (Site from CRA).	Heather Leary (b) (4)	09 Nov 2020 17:06:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	09 Nov 2020 17:06:18
User opened query 'Please update to include a stop date as dosing was changed due to AE. Create a stop date for the 10 mg dosing and a new ConMed line for the 80 mg as ongoing.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 15:57:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Aug 2020 17:47:03

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:20
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 12:56:30
User entered '29 Oct 2020' reason for change: Data Entry Error	Heather Leary (b) (4)	09 Nov 2020 17:06:18
User entered empty.	Afifah Ayub (b) (4)	04 Aug 2020 17:47:03

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:20
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:01:21
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Aug 2020 17:47:03

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:20
User entered '1'	System	04 Aug 2020 17:47:03

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:20
User entered '1'	System	04 Aug 2020 17:47:03

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:20
User entered '804 (804)'	System	04 Aug 2020 17:47:03

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:21:04
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION, ATC: LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS, PRODUCT: HYDROCHLOROTHIAZIDE;TRIAMTERENE, PRODUCTSYNONYM: TRIAMTERENE HCTZ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 17:50:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 17:50:00
Data point term sent to Coder	System	04 Aug 2020 17:49:09
User entered 'Triamterene HCTZ'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:48:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:21:06
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:48:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:21:09
User entered 'Hypertension'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:48:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:21:41
User entered '37.5-25'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:48:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:21:43
User entered 'mg (mg)'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:48:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:21:46
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:48:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:21:49
User entered 'once daily (QD)'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:48:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:21:51
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:48:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:21:52
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:48:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:21:53
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:48:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:21:11
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)	06 Aug 2020 12:40:24
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) (b) (4)	04 Aug 2020 21:05:16
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	04 Aug 2020 18:08:16
User entered 'UN UNK 2000'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:48:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:21:25
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:48:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:21:27
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:48:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:21:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:48:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:21:35
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:48:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 17:48:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 17:48:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 17:48:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:23:01
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 17:51:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 17:51:04
Data point term sent to Coder	System	04 Aug 2020 17:50:10
User entered 'Levothyroxine'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:49:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:23:02
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:49:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:23:05
User entered 'Hypothyroidism'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:49:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:23:06
User entered '50'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:49:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:23:08
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 04:06:04
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4) (b) (4)	22 Sep 2020 21:49:31
User entered 'ug (ug)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	22 Sep 2020 21:49:24
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 09:42:30
User entered 'mg (mg)'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:49:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:23:10
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:49:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:23:13
User entered 'once daily (QD)'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:49:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:23:14
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:49:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:23:16
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:49:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:23:18
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:49:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:23:19
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)	06 Aug 2020 12:40:34
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) (b) (4)	04 Aug 2020 21:05:37
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	04 Aug 2020 18:08:16
User entered 'UN UNK 2017'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:49:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:23:21
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:49:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:23:37
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:49:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:23:41
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:49:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:23:44
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 17:49:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 17:49:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 17:49:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 17:49:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:28
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 14:47:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 14:47:42
Data point term sent to Coder Coding entries removed.	System Reagan Reed (b) (4)	18 Dec 2020 14:46:47 18 Dec 2020 14:46:40
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 19:28:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 19:28:44
Data point term sent to Coder Coding entries removed.	System Heather Leary (b) (4)	10 Nov 2020 18:25:39 10 Nov 2020 18:25:31
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:23:53

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 03:56:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 03:56:54
Data point term sent to Coder	System	03 Sep 2020 21:26:13
User entered 'Advil (ibuprofen)'	Afifah Ayub (b) (4) (b) (4)	03 Sep 2020 21:26:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:28
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:24:01
User entered 'No (N)'	Afifah Ayub (b) (4)	03 Sep 2020 21:26:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:28
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User closed query 'Per CDM RQ: Response noted. Please confirm in query response that the solicited adverse reaction of FEVER/PAIN REACTOGENICITY (HEADACHE) did not meet the AE reporting criteria else clarify otherwise.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 08:31:21
Query 'Per CDM RQ: Response noted. Please confirm in query response that the solicited adverse reaction of FEVER/PAIN REACTOGENICITY (HEADACHE) did not meet the AE reporting criteria else clarify otherwise.' answered with 'SOLICITED AR DID NOT MEET AE REPORTING CRITERIA' (Site from DM).	Heather Leary (b) (4)	13 Jan 2021 17:15:36
User opened query 'Per CDM RQ: Response noted. Please confirm in query response that the solicited adverse reaction of FEVER/PAIN REACTOGENICITY (HEADACHE) did not meet the AE reporting criteria else clarify otherwise.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 09:09:31
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER/PAIN REACTOGENICITY (HEADACHE) is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER/PAIN REACTOGENICITY (HEADACHE) did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 09:08:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER/PAIN REACTOGENICITY (HEADACHE) is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER/PAIN REACTOGENICITY (HEADACHE) did not meet the AE reporting criteria.' answered with 'SAR due symptom starting and stopping within 7 days of vaccination ' (Site from DM).	Reagan Reed (b) (4)	18 Dec 2020 14:46:50
User entered 'FEVER/PAIN REACTOGENICITY' reason for change: Data Entry Error	Reagan Reed (b) (4)	18 Dec 2020 14:46:40
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER/PAIN REACTOGENICITY (HEADACHE) is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER/PAIN REACTOGENICITY (HEADACHE) did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 10:28:31
User closed query 'Per DM CLR: Please update the indication to reflect the location of PAIN REACTOGENICITY (e.g., GENERALIZED, BOTH LEGS, RIGHT ARM, etc) and type (e.g., JOINT, MUSCLE, etc) of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 19:24:37

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the indication to reflect the location of PAIN REACTOGENICITY (e.g., GENERALIZED, BOTH LEGS, RIGHT ARM, etc) and type (e.g., JOINT, MUSCLE, etc) of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'UPDATED' (Site from DM). DataPoint Un-verified.	Heather Leary (b) (4)	10 Nov 2020 18:25:37
	Heather Leary (b) (4)	10 Nov 2020 18:25:31
User entered 'FEVER/PAIN REACTOGENICITY (headache)' reason for change: Data Entry Error DataPoint Verified.	Heather Leary (b) (4)	10 Nov 2020 18:25:31
	(b) (4), (b) (6)	09 Nov 2020 16:27:09
User opened query 'Per DM CLR: Please update the indication to reflect the location of PAIN REACTOGENICITY (e.g., GENERALIZED, BOTH LEGS, RIGHT ARM, etc) and type (e.g., JOINT, MUSCLE, etc) of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 07:55:46
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER/PAIN REACTOGENICITY is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER/PAIN REACTOGENICITY did not meet the AE reporting criteria.' canceled (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 13:56:18

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER/PAIN REACTOGENICITY is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER/PAIN REACTOGENICITY did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 13:32:30
User entered 'fever/pain reactogenicity'	Afifah Ayub (b) (4)	03 Sep 2020 21:26:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:28
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:27:30
User entered '400'	Afifah Ayub (b) (4)	03 Sep 2020 21:26:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:28
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:27:33
User entered 'mg (mg)'	Afifah Ayub (b) (4)	03 Sep 2020 21:26:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:28
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:27:36
User entered empty.	Afifah Ayub (b) (4)	03 Sep 2020 21:26:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:28
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:27:40
User entered 'once (ONCE)'	Afifah Ayub (b) (4)	03 Sep 2020 21:26:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:28
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:27:42
User entered empty.	Afifah Ayub (b) (4)	03 Sep 2020 21:26:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:28
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:27:44
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4)	03 Sep 2020 21:26:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:28
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:28:03
User entered empty.	Afifah Ayub (b) (4)	03 Sep 2020 21:26:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:28
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	04 Dec 2020 19:07:02
User entered '02 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Dec 2020 19:07:02
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:28:12
User entered '2 Sep 2020'	Afifah Ayub (b) (4)	03 Sep 2020 21:26:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:28
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:28:14
User entered '0'	Afifah Ayub (b) (4)	03 Sep 2020 21:26:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:28
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:28:16
User entered 'No (N)'	Afifah Ayub (b) (4)	03 Sep 2020 21:26:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:28
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	04 Dec 2020 19:07:02
User entered '02 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Dec 2020 19:07:02
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:28:17
User entered '2 Sep 2020'	Afifah Ayub (b) (4)	03 Sep 2020 21:26:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:28
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER/PAIN REACTOGENICITY is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER/PAIN REACTOGENICITY did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 19:24:42
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:28:22
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER/PAIN REACTOGENICITY is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER/PAIN REACTOGENICITY did not meet the AE reporting criteria. ' answered with 'FEVER/PAIN REACTOGENICITY did not meet the AE reporting criteria.' (Site from DM).	Afifah Ayub (b) (4) (b) (4)	05 Oct 2020 16:18:06

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER/PAIN REACTOGENICITY is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER/PAIN REACTOGENICITY did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:50:23
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	03 Sep 2020 21:26:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:28
User entered empty.	System	03 Sep 2020 21:26:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:28
User entered empty.	System	03 Sep 2020 21:26:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:28
User entered empty.	System	03 Sep 2020 21:26:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:39
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:33:43
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 20:23:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 20:23:32
Data point term sent to Coder Coding entries removed.	System Anna Pena (b) (4)	26 Oct 2020 20:23:07 26 Oct 2020 20:23:06
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)	28 Sep 2020 20:06:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 20:06:42
Data point term sent to Coder User entered 'Influenza Vaccine'	System Afifah Ayub (b) (4)	28 Sep 2020 20:05:48 28 Sep 2020 20:05:46

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:39
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:33:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	04 Nov 2020 18:09:47
User entered 'No (N)'	Afifah Ayub (b) (4)	28 Sep 2020 20:05:46

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:39
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:33:52
User entered 'Immunization' reason for change: Data Entry Error	Anna Pena (b) (4)	26 Oct 2020 20:23:06
User entered 'Vaccination'	Afifah Ayub (b) (4)	28 Sep 2020 20:05:46

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:39
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:34:04
User entered '0.5' reason for change: Data Entry Error	Anna Pena (b) (4)	26 Oct 2020 20:23:06
User entered '1'	Afifah Ayub (b) (4)	28 Sep 2020 20:05:46

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:39
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:34:06
User entered 'mL (mL)' reason for change: Data Entry Error	Anna Pena (b) (4)	26 Oct 2020 20:23:06
User entered 'Other (OTHER)'	Afifah Ayub (b) (4)	28 Sep 2020 20:05:46

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:39
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:34:08
User entered empty; reason for change Data Entry Error	Anna Pena (b) (4)	26 Oct 2020 20:23:06
User entered 'Vaccine'	Afifah Ayub (b) (4)	28 Sep 2020 20:05:46

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:39
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:34:09
User entered 'once (ONCE)'	Afifah Ayub (b) (4)	28 Sep 2020 20:05:46

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:39
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:34:10
User entered empty.	Afifah Ayub (b) (4)	28 Sep 2020 20:05:46

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:39
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:34:12
User entered 'Intramuscular (INTRAMUSCULAR)'	Afifah Ayub (b) (4)	28 Sep 2020 20:05:46

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:39
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:34:14
User entered empty.	Afifah Ayub (b) (4)	28 Sep 2020 20:05:46

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:39
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:34:16
User entered '16 Sep 2020'	Afifah Ayub (b) (4)	28 Sep 2020 20:05:46

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:39
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:34:18
User entered '0'	Afifah Ayub (b) (4)	28 Sep 2020 20:05:46

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:39
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:34:20
User entered 'No (N)'	Afifah Ayub (b) (4)	28 Sep 2020 20:05:46

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:39
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:34:22
User entered '16 Sep 2020'	Afifah Ayub (b) (4)	28 Sep 2020 20:05:46

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:39
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:34:25
User entered 'No (N)'	Afifah Ayub (b) (4)	28 Sep 2020 20:05:46

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:39
User entered empty.	System	28 Sep 2020 20:05:46

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:39
User entered empty.	System	28 Sep 2020 20:05:46

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:39
User entered empty.	System	28 Sep 2020 20:05:46

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:47
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:36:14
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: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PANTOPRAZOLE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 18:12:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 18:12:28
Data point term sent to Coder	System	04 Nov 2020 18:11:22
User entered 'Pantoprazole Sodium Dr'	Afifah Ayub (b) (4)	04 Nov 2020 18:10:33

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:47
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:36:16
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Nov 2020 18:10:33

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:47
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:36:18
User entered 'Gastroesophageal reflux disease'	Afifah Ayub (b) (4)	04 Nov 2020 18:10:33

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:47
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:36:20
User entered '40'	Afifah Ayub (b) (4)	04 Nov 2020 18:10:33

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:47
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:36:22
User entered 'mg (mg)'	Afifah Ayub (b) (4)	04 Nov 2020 18:10:33

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:47
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:36:24
User entered empty.	Afifah Ayub (b) (4)	04 Nov 2020 18:10:33

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:47
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:36:26
User entered 'once daily (QD)'	Afifah Ayub (b) (4)	04 Nov 2020 18:10:33

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:47
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:36:28
User entered empty.	Afifah Ayub (b) (4)	04 Nov 2020 18:10:33

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:47
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:36:29
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4)	04 Nov 2020 18:10:33

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:47
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:36:32
User entered empty.	Afifah Ayub (b) (4)	04 Nov 2020 18:10:33

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:47
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:36:33
User entered '28 Oct 2020'	Afifah Ayub (b) (4)	04 Nov 2020 18:10:33

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:47
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:36:35
User entered '0'	Afifah Ayub (b) (4)	04 Nov 2020 18:10:33

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:47
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Un-verified.	Afifah Ayub (b) (4)	04 Dec 2020 17:46:26
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	04 Dec 2020 17:46:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:36:36
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Nov 2020 18:10:33

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:47
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Un-verified.	Afifah Ayub (b) (4)	04 Dec 2020 17:46:26
User entered '11 Nov 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	04 Dec 2020 17:46:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:36:38
User entered empty.	Afifah Ayub (b) (4)	04 Nov 2020 18:10:33

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:47
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:36:44
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Nov 2020 18:10:33

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:47
User entered '1'	System	04 Nov 2020 18:10:33

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:47
User entered '1'	System	04 Nov 2020 18:10:33

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:47
User entered '804 (804)'	System	04 Nov 2020 18:10:33

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:37:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 19:24:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 19:24:28
Data point term sent to Coder	System	04 Nov 2020 18:11:24
User entered 'Amiodarone'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:11:22

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:37:06
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:11:22

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:37:09
User entered 'Coronary artery disease'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:11:22

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:38:12
User entered '200'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:11:22

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:38:14
User entered 'mg (mg)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:11:22

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:38:16
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:11:22

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:38:17
User entered 'once daily (QD)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:11:22

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:38:19
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:11:22

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:38:21
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:11:22

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:38:23
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:11:22

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:38:25
User entered '29 Oct 2020'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:11:22

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:38:27
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:11:22

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:38:28
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:11:22

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:38:32
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:11:22

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:38:34
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:11:22

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 18:11:22

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 18:11:22

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Nov 2020 18:11:22

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:55
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:38:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 18:58:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 18:58:26
Data point term sent to Coder	System	04 Nov 2020 18:12:28
User entered 'Gabapentin'	Afifah Ayub (b) (4)	04 Nov 2020 18:12:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:55
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:38:42
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Nov 2020 18:12:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:55
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
User closed query 'Per CDM RQ: Response noted 'see procedure log', however, there is no AE that matches this Con Med indication 'POST OPERATIVE PAIN, CORONARY ARTERY BYPASS GRAFT' during this timeframe? Please review and add an entry and applicable details to the AE eCRF as appropriate or, provide AE record number this indication pertains to. Thanks.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 08:50:02
Query 'Per CDM RQ: Response noted 'see procedure log', however, there is no AE that matches this Con Med indication 'POST OPERATIVE PAIN, CORONARY ARTERY BYPASS GRAFT' during this timeframe? Please review and add an entry and applicable details to the AE eCRF as appropriate or, provide AE record number this indication pertains to. Thanks.' answered with 'AE 5 post operative pain' (Site from DM).	Heather Leary (b) (4)	15 Jan 2021 21:45:46
User opened query 'Per CDM RQ: Response noted 'see procedure log', however, there is no AE that matches this Con Med indication 'POST OPERATIVE PAIN, CORONARY ARTERY BYPASS GRAFT' during this timeframe? Please review and add an entry and applicable details to the AE eCRF as appropriate or, provide AE record number this indication pertains to. Thanks.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 09:25:46
Query 'Per CDM RQ: Response noted 'see procedure log', however, there is no AE that matches this Con Med indication 'POST OPERATIVE PAIN' during this timeframe? Please review and add an entry and applicable details to the AE eCRF as appropriate or, provide AE record number this indication pertains to. Thanks.' canceled (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 09:25:22

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per CDM RQ: Response noted 'see procedure log', however, there is no AE that matches this Con Med indication 'POST OPERATIVE PAIN' during this timeframe? Please review and add an entry and applicable details to the AE eCRF as appropriate or, provide AE record number this indication pertains to. Thanks.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 09:21:38
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 09:11:02
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' answered with 'see procedure log ' (Site from DM).	Reagan Reed (b) (4)	18 Dec 2020 14:46:20
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 10:30:09
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:38:46
User entered 'Post operative pain, coronary artery bypass graft'	Afifah Ayub (b) (4)	04 Nov 2020 18:12:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:55
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:39:07
User entered '100'	Afifah Ayub (b) (4)	04 Nov 2020 18:12:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:55
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:39:09
User entered 'mg (mg)'	Afifah Ayub (b) (4)	04 Nov 2020 18:12:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:55
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:39:11
User entered empty.	Afifah Ayub (b) (4)	04 Nov 2020 18:12:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:55
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:39:14
User entered 'three times daily (TID)'	Afifah Ayub (b) (4)	04 Nov 2020 18:12:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:55
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:39:16
User entered empty.	Afifah Ayub (b) (4)	04 Nov 2020 18:12:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:55
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:39:17
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4)	04 Nov 2020 18:12:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:55
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:39:19
User entered empty.	Afifah Ayub (b) (4)	04 Nov 2020 18:12:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:55
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:39:22
User entered '28 Oct 2020'	Afifah Ayub (b) (4)	04 Nov 2020 18:12:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:55
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:40:25
User entered '0'	Afifah Ayub (b) (4)	04 Nov 2020 18:12:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:55
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Un-verified.	Afifah Ayub (b) (4)	04 Dec 2020 17:41:29
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	04 Dec 2020 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:40:28
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Nov 2020 18:12:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:55
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Un-verified.	Afifah Ayub (b) (4)	04 Dec 2020 17:41:29
User entered '11 Nov 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	04 Dec 2020 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:40:34
User entered empty.	Afifah Ayub (b) (4)	04 Nov 2020 18:12:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:55
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:40:36
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Nov 2020 18:12:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:55
User entered '3'	System	04 Nov 2020 18:12:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:55
User entered '1'	System	04 Nov 2020 18:12:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:55
User entered '804 (804)'	System	04 Nov 2020 18:12:07

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:40:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 18:14:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 18:14:26
Data point term sent to Coder	System	04 Nov 2020 18:13:30
User entered 'Metoprolol'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:12:38

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:40:44
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:12:38

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:40:46
User entered 'Hypertension'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:12:38

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:40:49
User entered '25'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:12:38

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:40:50
User entered 'mg (mg)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:12:38

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:40:51
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:12:38

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:40:53
User entered 'once daily (QD)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:12:38

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:40:55
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:12:38

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:40:58
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:12:38

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:03
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:12:38

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:06
User entered '29 Oct 2020'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:12:38

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:08
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:12:38

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:12:38

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:11
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:12:38

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:13
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Nov 2020 18:12:38

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 18:12:38

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 18:12:38

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Nov 2020 18:12:38

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
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) (b) (4)	09 Nov 2020 17:38:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 17:38:34
Data point term sent to Coder	System	09 Nov 2020 17:08:03
User entered 'Atorvastatin'	Heather Leary (b) (4) (b) (4)	09 Nov 2020 17:07:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	09 Nov 2020 17:07:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'hypercholesterolemia'	Heather Leary (b) (4) (b) (4)	09 Nov 2020 17:07:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered '80'	Heather Leary (b) (4) (b) (4)	09 Nov 2020 17:07:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'mg (mg)'	Heather Leary (b) (4) (b) (4)	09 Nov 2020 17:07:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Nov 2020 17:07:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'once daily (QD)'	Heather Leary (b) (4) (b) (4)	09 Nov 2020 17:07:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Nov 2020 17:07:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'Oral (ORAL)'	Heather Leary (b) (4) (b) (4)	09 Nov 2020 17:07:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Nov 2020 17:07:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered '29 Oct 2020'	Heather Leary (b) (4) (b) (4)	09 Nov 2020 17:07:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered '0'	Heather Leary (b) (4) (b) (4)	09 Nov 2020 17:07:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	09 Nov 2020 17:07:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Nov 2020 17:07:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	09 Nov 2020 17:07:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 17:07:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 17:07:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Nov 2020 17:07:25

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
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) (b) (4)	19 Jan 2021 14:45:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Jan 2021 14:45:07
Data point term sent to Coder	System	19 Jan 2021 14:43:28
Coding entries removed.	Reagan Reed (b) (4) (b) (4)	19 Jan 2021 14:42:28
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) (b) (4)	04 Dec 2020 19:42:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Dec 2020 19:42:03
Data point term sent to Coder	System	04 Dec 2020 17:42:32
User entered 'Aspirin'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User closed query 'Per DM CLR: Please update the indication of this medication to include the term Prophylaxis and the medical condition being prevented (e.g. CARDIAC prophylaxis). Update Con Med eCRF as appropriate.' (Site from DM). Query 'Per DM CLR: Please update the indication of this medication to include the term Prophylaxis and the medical condition being prevented (e.g. CARDIAC prophylaxis). Update Con Med eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6) Reagan Reed (b) (4) (b) (4)	19 Jan 2021 17:51:38 19 Jan 2021 14:42:41
User entered 'CARDIAC Prophylaxis' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	19 Jan 2021 14:42:28
User opened query 'Per DM CLR: Please update the indication of this medication to include the term Prophylaxis and the medical condition being prevented (e.g. CARDIAC prophylaxis). Update Con Med eCRF as appropriate.' (Site from DM). User entered 'cardiac; general health'	(b) (4), (b) (6) Afifah Ayub (b) (4) (b) (4)	19 Jan 2021 13:13:54 04 Dec 2020 17:42:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered '81'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'mg (mg)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'once daily (QD)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'UN UNK 2005'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 17:42:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 17:42:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Dec 2020 17:42:21

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: COMBINATIONS OF VITAMINS, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Jan 2021 22:44:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Jan 2021 22:44:10
Data point term sent to Coder	System	19 Jan 2021 14:44:28
Coding entries removed.	Reagan Reed (b) (4) (b) (4)	19 Jan 2021 14:43:43
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Dec 2020 20:47:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Dec 2020 20:47:52
Data point term sent to Coder	System	04 Dec 2020 17:43:39
User entered 'Centrum Complete Multivitamin'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:50

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:50

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User closed query 'Per DM CLR: Please update the indication of this medication to include the term Prophylaxis and the medical condition being prevented (e.g. ILLNESS prophylaxis). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 17:52:33
Query 'Per DM CLR: Please update the indication of this medication to include the term Prophylaxis and the medical condition being prevented (e.g. ILLNESS prophylaxis). Update Con Med eCRF as appropriate.' answered with 'updated' (Site from DM).	Reagan Reed (b) (4) (b) (4)	19 Jan 2021 14:43:52
User entered 'ILLNESS Prophylaxis' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	19 Jan 2021 14:43:43
User opened query 'Per DM CLR: Please update the indication of this medication to include the term Prophylaxis and the medical condition being prevented (e.g. ILLNESS prophylaxis). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 13:23:23
User entered 'illness; General Health'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:50

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered '1'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:50

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'tablet (TABLET)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:50

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:50

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'once daily (QD)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:50

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:50

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:50

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:50

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'UN UNK 2000'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:50

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:50

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:50

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:50

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:42:50

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 17:42:50

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 17:42:50

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Dec 2020 17:42:50

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
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: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Jan 2021 14:46:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Jan 2021 14:46:05
Data point term sent to Coder Coding entries removed.	System Reagan Reed (b) (4) (b) (4)	19 Jan 2021 14:45:29 19 Jan 2021 14:44:37
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: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Dec 2020 17:45:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Dec 2020 17:45:33
Data point term sent to Coder User entered 'Vitamin D3'	System Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:43:41 04 Dec 2020 17:43:31

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:43:31

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User closed query 'Per DM CLR: Please update the indication of this medication to include the term Prophylaxis and the medical condition being prevented (e.g. VITAMIN D DEFICIENCY prophylaxis). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 17:52:42
Query 'Per DM CLR: Please update the indication of this medication to include the term Prophylaxis and the medical condition being prevented (e.g. VITAMIN D DEFICIENCY prophylaxis). Update Con Med eCRF as appropriate.' answered with 'updated' (Site from DM).	Reagan Reed (b) (4) (b) (4)	19 Jan 2021 14:44:43
User entered 'VITAMIN D DEFICIENCY Prophylaxis' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	19 Jan 2021 14:44:37
User opened query 'Per DM CLR: Please update the indication of this medication to include the term Prophylaxis and the medical condition being prevented (e.g. VITAMIN D DEFICIENCY prophylaxis). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 13:58:38
User entered 'Vitamin D deficiency; general health'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:43:31

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered '1000'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:43:31

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'IU (IU)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:43:31

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:43:31

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User closed query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 17:52:46
Query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify.' answered with 'updated' (Site from DM).	Reagan Reed (b) (4) (b) (4)	19 Jan 2021 14:44:49
User entered 'once daily (QD)' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	19 Jan 2021 14:44:37
User opened query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 13:58:56
User entered 'once (ONCE)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:43:31

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:43:31

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:43:31

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:43:31

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'UN UNK 2000'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:43:31

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:43:31

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:43:31

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:43:31

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:43:31

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Jan 2021 14:44:37
User entered empty.	System	04 Dec 2020 17:43:31

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Jan 2021 14:44:37
User entered empty.	System	04 Dec 2020 17:43:31

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Jan 2021 14:44:37
User entered empty.	System	04 Dec 2020 17:43:31

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Jan 2021 15:04:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Jan 2021 15:04:07
Data point term sent to Coder	System	19 Jan 2021 14:45:29
Coding entries removed.	Reagan Reed (b) (4) (b) (4)	19 Jan 2021 14:45:17
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 10:46:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 10:46:50
Data point term sent to Coder	System	04 Dec 2020 17:44:43
User entered 'Folic Acid'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User closed query 'Per CDM: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 13:26:31
Query 'Per CDM: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'please see the audit trail before rendering senseless requeries	Reagan Reed (b) (4) (b) (4)	23 Feb 2021 17:34:46
this subject does NOT have a folic acid deficiency - therefore this medication and indication is entered properly, and you would NOT see a med hx or adverse event item entered. Please also see DM CLR audit trail telling the site to add prophylaxis to this medication indication despite the EDC entry line "prophylaxis" being marked yes. The site is not subject to every whim of DM with EDC. This entry will remain as it is entered. ' (Site from DM).		
User opened query 'Per CDM: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 12:14:45
User closed query 'Per DM CLR re-query: Response is noted, however, this condition is still not recorded on the MH eCRF and remove the term 'PROPHYLAXIS'. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 12:11:13

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR re-query: Response is noted, however, this condition is still not recorded on the MH eCRF and remove the term 'PROPHYLAXIS'. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'this subject does NOT have a folic acid deficiency - therefore this medication and indication is entered properly, and you would NOT see a med hx or adverse event item entered. Please also see DM CLR audit trail telling the site to add prophylaxis to this medication indication despite the EDC entry line "prophylaxis" being marked yes. The site is not subject to every whim of DM with EDC. This entry will remain as it is entered.' (Site from DM).	Reagan Reed (b) (4)	22 Feb 2021 15:27:19
User opened query 'Per DM CLR re-query: Response is noted, however, this condition is still not recorded on the MH eCRF and remove the term 'PROPHYLAXIS'. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 05:23:09
User closed query 'Per DM CLR: Please update the indication of this medication to include the term Prophylaxis and the medical condition being prevented (e.g. FOLIC ACID DEFICIENCY prophylaxis). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 17:59:50
Query 'Per DM CLR: Please update the indication of this medication to include the term Prophylaxis and the medical condition being prevented (e.g. FOLIC ACID DEFICIENCY prophylaxis). Update Con Med eCRF as appropriate.' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	19 Jan 2021 14:45:22
User entered 'FOLIC ACID DEFICIENCY prophylaxis' reason for change: Data Entry Error	Reagan Reed (b) (4)	19 Jan 2021 14:45:17
User opened query 'Per DM CLR: Please update the indication of this medication to include the term Prophylaxis and the medical condition being prevented (e.g. FOLIC ACID DEFICIENCY prophylaxis). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 13:59:22

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User entered 'deficiency prophylaxis; general health'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered '800'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'ug (ug)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'once daily (QD)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'Un UNK 2000'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 17:44:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 17:44:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Dec 2020 17:44:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: CHONDROITIN;GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 20:30:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 20:30:46
Data point term sent to Coder	System	04 Dec 2020 17:44:42
User entered 'glucosamine-chondroitin'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:35

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:35

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

Indication

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
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 and confirm if it refers to JOINT HEALTH. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 18:00:05
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication and confirm if it refers to JOINT HEALTH. Update Con Med eCRF as appropriate.' answered with 'this is a general health supplement to maintain healthy joints. no update needed' (Site from DM).	Reagan Reed (b) (4) (b) (4)	19 Jan 2021 14:46:04
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 and confirm if it refers to JOINT HEALTH. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 14:00:07
User entered 'joint; general health'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:35

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 18:00:08
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' answered with 'updated' (Site from DM).	Reagan Reed (b) (4) (b) (4)	19 Jan 2021 14:49:26
User entered '500-400' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	19 Jan 2021 14:48:52
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 14:00:25
User entered '50'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:35

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 18:00:12
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).	Reagan Reed (b) (4) (b) (4)	19 Jan 2021 14:49:31
User entered 'mg (mg)' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	19 Jan 2021 14:48:52
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 14:00:38
User entered 'ug (ug)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:35

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:35

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'once daily (QD)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:35

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:35

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:35

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:35

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'UN UNK 2000'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:35

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:35

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:35

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:35

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:44:35

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 17:44:35

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 17:44:35

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Dec 2020 17:44:35

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:45:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION, ATC: LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS, PRODUCT: HYDROCHLOROTHIAZIDE;TRIAMTERENE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Dec 2020 17:45:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Dec 2020 17:45:58
Data point term sent to Coder	System	04 Dec 2020 17:45:43
User entered 'triamterene-hydrochlorothiazide'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:45:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:45:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'hypertension'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:45:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered '37.5-25'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:45:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'mg (mg)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:45:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:45:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:45:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'once daily (QD)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:45:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:45:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:45:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:45:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:45:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:45:33

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'UN UNK 2010'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:45:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:45:33

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered '0'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:45:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:45:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:45:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:45:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 17:45:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 17:45:04

US3212028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Dec 2020 17:45:04

US3212028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:45:33

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:27:53
User signature succeeded.	Vicki Miller (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:57:24
User entered 'Yes (Y)' reason for change: New Information	Heather Leary (b) (4)	28 Oct 2020 15:40:50
User entered 'No (N)'	Afifah Ayub (b) (4)	04 Aug 2020 17:45:38

US3212028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:45:33

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:57:38
User entered '23 Oct 2020'	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:41:12

US3212028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:45:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:57:41
User entered 'coronary artery bypass graft'	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:41:12

US3212028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User closed query 'Per CDM: Please review the procedure for ACUTE CORONARY SYNDROME (NON ST ELEVATED MYOCARDIAL INFARCTION) is recorded in the AE #1 page, Kindly review the Indication and update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 10:40:25
Query 'Per CDM: Please review the procedure for ACUTE CORONARY SYNDROME (NON ST ELEVATED MYOCARDIAL INFARCTION) is recorded in the AE #1 page, Kindly review the Indication and update accordingly, else clarify.' answered with 'updated' (Site from DM).	Reagan Reed (b) (4) (b) (4)	24 Nov 2020 15:17:01
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	24 Nov 2020 15:16:54
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	24 Nov 2020 15:16:45
DataPoint Un-verified.	Reagan Reed (b) (4) (b) (4)	24 Nov 2020 15:16:45
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	24 Nov 2020 15:16:45
User opened query 'Per CDM: Please review the procedure for ACUTE CORONARY SYNDROME (NON ST ELEVATED MYOCARDIAL INFARCTION) is recorded in the AE #1 page, Kindly review the Indication and update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 15:06:49
User closed query 'Please update indication to Coronary Artery Disease.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 15:57:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:57:35
Query 'Please update indication to Coronary Artery Disease.' answered with 'Updated' (Site from CRA).	Reagan Reed (b) (4) (b) (4)	10 Nov 2020 13:56:02
User entered 'Other (OTHER)' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	10 Nov 2020 13:55:37
User opened query 'Please update indication to Coronary Artery Disease.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 12:58:41

US3212028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per source, indication for Concomitant Procedure is Coronary Artery Disease. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 12:58:41
Query 'Per source, indication for Concomitant Procedure is Coronary Artery Disease. Please verify with source and update EDC accordingly.' answered with 'updated ' (Site from CRA).	Reagan Reed (b) (4)	09 Nov 2020 17:02:34
User opened query 'Per source, indication for Concomitant Procedure is Coronary Artery Disease. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 16:58:24
User entered 'Adverse Event (AE)'	Heather Leary (b) (4)	28 Oct 2020 15:41:12

US3212028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:45:33

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	29 Mar 2021 19:12:29
User entered empty; reason for change Data Entry Error	Reagan Reed (b) (4) (b) (4)	24 Nov 2020 15:16:54
DataPoint Un-verified.	Reagan Reed (b) (4) (b) (4)	23 Nov 2020 22:08:40
User entered 'acute coronary syndrome (non ST Elevated Myocardial Infarction)' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	23 Nov 2020 22:08:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:57:42
DataPoint Un-verified.	Reagan Reed (b) (4) (b) (4)	10 Nov 2020 13:55:37
User entered 'Coronary Artery Disease' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	10 Nov 2020 13:55:37
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:58:28
User entered empty.	Heather Leary (b) (4) (b) (4)	28 Oct 2020 15:41:12

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'USA-US115-2020-MRNA-1273-P301000007'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:40
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Yes (Y)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:50
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:44
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Yes (Y)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:56
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Vicki'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:01
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Miller'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:03
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:43:02
User entered 'US'	System	29 Oct 2020 13:24:18

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	10 Dec 2020 14:31:34
User entered '5'	System	06 Dec 2020 16:24:11
User entered '4'	System	24 Nov 2020 19:45:13
User entered '3'	System	19 Nov 2020 16:40:58
User entered '2'	System	09 Nov 2020 14:43:14
User entered '1'	System	29 Oct 2020 13:24:18

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'USA-US115-2020-MRNA-1273-P301000007'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:40
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Yes (Y)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:50
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:44
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Yes (Y)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:56
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Vicki'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:01
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Miller'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:03
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:43:02
User entered 'US'	System	29 Oct 2020 13:24:18

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	10 Dec 2020 14:31:34
User entered '5'	System	06 Dec 2020 16:24:11
User entered '4'	System	24 Nov 2020 19:45:13
User entered '3'	System	19 Nov 2020 16:40:58
User entered '2'	System	09 Nov 2020 14:43:14
User entered '1'	System	29 Oct 2020 13:24:18

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:45:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:47:12
User entered '29/Oct/2020 13:24'	System	29 Oct 2020 13:24:18

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:45:33

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:47:14
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:43:02
User entered 'I'	(b) (4), (b) (6)	29 Oct 2020 13:24:18

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'USA-US115-2020-MRNA-1273-P301000007'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:40
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Yes (Y)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:50
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:44
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Yes (Y)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:56
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Vicki'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:01
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Miller'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:03
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:43:02
User entered 'US'	System	29 Oct 2020 13:24:18

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	10 Dec 2020 14:31:34
User entered '5'	System	06 Dec 2020 16:24:11
User entered '4'	System	24 Nov 2020 19:45:13
User entered '3'	System	19 Nov 2020 16:40:58
User entered '2'	System	09 Nov 2020 14:43:14
User entered '1'	System	29 Oct 2020 13:24:18

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:45:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:47:18
User entered '09/Nov/2020 14:43'	System	09 Nov 2020 14:43:14

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:45:33

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:40:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:47:20
User entered 'I'	(b) (4), (b) (6)	09 Nov 2020 14:43:14

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'USA-US115-2020-MRNA-1273-P301000007'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:40
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Yes (Y)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:50
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:44
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Yes (Y)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:56
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Vicki'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:01
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Miller'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:03
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:43:02
User entered 'US'	System	29 Oct 2020 13:24:18

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	10 Dec 2020 14:31:34
User entered '5'	System	06 Dec 2020 16:24:11
User entered '4'	System	24 Nov 2020 19:45:13
User entered '3'	System	19 Nov 2020 16:40:58
User entered '2'	System	09 Nov 2020 14:43:14
User entered '1'	System	29 Oct 2020 13:24:18

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:45:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
	(b) (4)	
User entered '19/Nov/2020 11:40'	System	19 Nov 2020 16:40:58

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:45:33

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:45:04
User entered 'I'	(b) (4), (b) (6)	19 Nov 2020 16:40:58

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'USA-US115-2020-MRNA-1273-P301000007'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:40
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Yes (Y)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:50
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:44
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Yes (Y)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:56
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Vicki'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:01
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Miller'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:03
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:43:02
User entered 'US'	System	29 Oct 2020 13:24:18

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	10 Dec 2020 14:31:34
User entered '5'	System	06 Dec 2020 16:24:11
User entered '4'	System	24 Nov 2020 19:45:13
User entered '3'	System	19 Nov 2020 16:40:58
User entered '2'	System	09 Nov 2020 14:43:14
User entered '1'	System	29 Oct 2020 13:24:18

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:45:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
	(b) (4)	
User entered '24/Nov/2020 19:45'	System	24 Nov 2020 19:45:13

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:45:33

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 16:23:51
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 19:45:13

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'USA-US115-2020-MRNA-1273-P301000007'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:40
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Yes (Y)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:50
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:44
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Yes (Y)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:56
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Vicki'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:01
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Miller'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:03
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:43:02
User entered 'US'	System	29 Oct 2020 13:24:18

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	10 Dec 2020 14:31:34
User entered '5'	System	06 Dec 2020 16:24:11
User entered '4'	System	24 Nov 2020 19:45:13
User entered '3'	System	19 Nov 2020 16:40:58
User entered '2'	System	09 Nov 2020 14:43:14
User entered '1'	System	29 Oct 2020 13:24:18

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:45:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
	(b) (4)	
User entered '06/Dec/2020 16:24'	System	06 Dec 2020 16:24:11

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:45:33

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 14:31:22
User entered 'I'	(b) (4), (b) (6)	06 Dec 2020 16:24:11

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'USA-US115-2020-MRNA-1273-P301000007'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:40
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Yes (Y)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:50
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:44
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Yes (Y)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:56
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'No (N)'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Vicki'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:01
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:23:23
User entered 'Miller'	System	29 Oct 2020 13:23:01

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:03
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:43:02
User entered 'US'	System	29 Oct 2020 13:24:18

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	10 Dec 2020 14:31:34
User entered '5'	System	06 Dec 2020 16:24:11
User entered '4'	System	24 Nov 2020 19:45:13
User entered '3'	System	19 Nov 2020 16:40:58
User entered '2'	System	09 Nov 2020 14:43:14
User entered '1'	System	29 Oct 2020 13:24:18

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:45:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:18:00
	(b) (4)	
User entered '10/Dec/2020 14:31'	System	10 Dec 2020 14:31:34

US3212028

Folder: SAE USA-US115-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:45:33

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	01 Apr 2021 19:18:00
User entered 'I'	(b) (4), (b) (6)	10 Dec 2020 14:31:34