

US3212100 (Prod: DM Clinical Research - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:47:13

All time stamps listed in this document are displayed in GMT

US3212100

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

[Participant ID](#)

US3212100

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

US3212100

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Date of Birth (MMM yyyy)	(b) (6) 1981
Age	38
Age Units	YEARS
Age (Derived)	38
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Date of Informed Consent (<i>dd MMM yyyy</i>)	10 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Mar 2021 18:13:59

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Mar 2021 18:13:59

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Condition	PREDIABETES
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3212100

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Condition	SEASONAL ALLERGIC RHINITIS
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)	_____

US3212100

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Condition	CHOLECYSTITIS
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

US3212100

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Condition	LEIOMYOMA OF UTERUS
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)	_____

US3212100

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:42 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 09:42
Height (<i>xxx.x</i>)	62 in
Weight (<i>xxx.x</i>)	157 lb
BMI (<i>xxx.x</i>)	28.77572 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 18:13:59

Generated On: 09 Jun 2021 15:47:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 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: Childbearing Potential

Data signed: (b) (4) 26 Mar 2021 18:13:59

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Date of assessment (dd MMM yyyy) 10 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 10 AUG 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Mar 2021 18:13:59

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

COLLEGE PROFESSOR

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 18:13:59

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	PEOPLE IN THE PARTICIPANT'S WORKPLACE ARE NOT REGULARLY USING PERSONAL PROTECTION EQUIPMENT. PARTICIPANT GOES IN PERSON TO THEIR MAIN WORKPLACE MORE THAN 2 DAYS/WEEK...

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

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

Visit date (dd MMM yyyy)	10 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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US3212100

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

What was the date of randomization? (dd MMM yyyy) 10 AUG 2020

What was the participant's randomization number? 102571

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

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 18:13:59

Generated On: 09 Jun 2021 15:47:13

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)	10 AUG 2020
Time of assessment (00:00-23:59)	09:42 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 09:42
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPO
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

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)	10 AUG 2020
Time of assessment (00:00-23:59)	11:58 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 11:58
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 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 18:13:59

Generated On: 09 Jun 2021 15:47:13

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

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) 10 AUG 2020

What was the treatment time? (00:00-23:59) 11:28 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 11:28

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 18:13:59

Generated On: 09 Jun 2021 15:47:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 AUG 2020
Collection time (00:00-23:59)	11:09 (24 HR)
Collection date and time (derived)	10 AUG 2020 11:09

US3212100

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Collection date (dd MMM yyyy)			10 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:04	10 AUG 2020 11:04
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

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

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 11:56

PC Open Date & Time

10 AUG 2020 11:48

PC Close Date & Time

10 AUG 2020 14:18

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

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 99.0 °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	10 AUG 2020 15:41
PC Open Date & Time	10 AUG 2020 15:13
PC Close Date & Time	11 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:47:13

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

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 14:05

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:47:13

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

99.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 14:58

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

13 AUG 2020 13:02

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:47:13

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

99.0 °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

14 AUG 2020 15:41

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:47:13

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

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 13:01

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:47:13

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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	16 AUG 2020 15:55
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 14:44

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 11:57

PC Open Date & Time

10 AUG 2020 11:48

PC Close Date & Time

10 AUG 2020 14:18

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

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

10 AUG 2020 15:41

PC Open Date & Time

10 AUG 2020 15:13

PC Close Date & Time

11 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 14:04

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 14:57

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:47:13

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

13 AUG 2020 13:03

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:47:13

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

14 AUG 2020 15:42

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:47:13

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

15 AUG 2020 13:00

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 15:56

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 11:58
PC Open Date & Time	10 AUG 2020 11:48
PC Close Date & Time	10 AUG 2020 14:18

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 15:42
PC Open Date & Time	10 AUG 2020 15:13
PC Close Date & Time	11 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 2539

EAB) (1725)

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

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

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2539

EAB) (1725)

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 14:58
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2539

EAB) (1725)

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 13:03
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 15:42
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

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

58 of 2539

EAB) (1725)

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 13:01
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

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

60 of 2539

EAB) (1725)

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 15:55
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 8

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 ☐

PC Time Stamp 17 AUG 2020 14:43

PC Open Date & Time 17 AUG 2020 12:00

PC Close Date & Time 18 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 9

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 ☐

PC Time Stamp 18 AUG 2020 12:55

PC Open Date & Time 18 AUG 2020 12:00

PC Close Date & Time 19 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 10

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 ☐

PC Time Stamp 19 AUG 2020 13:52

PC Open Date & Time 19 AUG 2020 12:00

PC Close Date & Time 20 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(11)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 11

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 ☐

PC Time Stamp 20 AUG 2020 12:11

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp 17 AUG 2020 14:43

PC Open Date & Time 17 AUG 2020 12:00

PC Close Date & Time 18 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 AUG 2020 14:43
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 AUG 2020 12:55
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 AUG 2020 13:52
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3212100

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 AUG 2020 12:11
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3212100

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3212100

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212100

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 18:13:58

Generated On: 09 Jun 2021 15:47:13

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3212100

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 18:13:58

Generated On: 09 Jun 2021 15:47:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212100

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 18:13:58

Generated On: 09 Jun 2021 15:47:13

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3212100

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 18:13:58

Generated On: 09 Jun 2021 15:47:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212100

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

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

Visit date (dd MMM yyyy)	08 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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US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

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)	08 SEP 2020
Time of assessment (00:00-23:59)	13:12 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 13:12
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

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)	08 SEP 2020
Time of assessment (00:00-23:59)	15:17 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 15:17
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3212100

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

US3212100

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	8 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3212100

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

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) 08 SEP 2020

What was the treatment time? (00:00-23:59) 14:07 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 14:07

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

US3212100

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 08 SEP 2020

Collection time (00:00-23:59) 14:02 (24 HR)

Collection date and time (derived) 08 SEP 2020 14:02

US3212100

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Collection date (dd MMM yyyy)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:58	08 SEP 2020 13:58
Nasopharyngeal Swab 2	No		

US3212100

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 15:16

PC Open Date & Time

08 SEP 2020 14:27

PC Close Date & Time

08 SEP 2020 16:57

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.9 °F

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

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

PC Time Stamp	08 SEP 2020 17:57
PC Open Date & Time	08 SEP 2020 17:52
PC Close Date & Time	09 SEP 2020 11:59

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

09 SEP 2020 12:03

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 12:45

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

11 SEP 2020 13:27

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 12:12

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 16:16

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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):

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

False

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

14 SEP 2020 15:02

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 12:37

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 15:17

PC Open Date & Time

08 SEP 2020 14:27

PC Close Date & Time

08 SEP 2020 16:57

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 17:55

PC Open Date & Time

08 SEP 2020 17:52

PC Close Date & Time

09 SEP 2020 11:59

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:47:13

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

09 SEP 2020 12:06

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:47:13

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

10 SEP 2020 12:46

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:47:13

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

11 SEP 2020 13:28

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:47:13

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

12 SEP 2020 12:13

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:47:13

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

13 SEP 2020 16:16

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:47:13

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

14 SEP 2020 15:02

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 15:17
PC Open Date & Time	08 SEP 2020 14:27
PC Close Date & Time	08 SEP 2020 16:57

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 17:56
PC Open Date & Time	08 SEP 2020 17:52
PC Close Date & Time	09 SEP 2020 11:59

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

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 ☒

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 12:05
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

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 ☒

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 12:45
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☒

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 13:28
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

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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US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

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

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 16:16
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 15:02
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3212100

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 SEP 2020 12:37
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3212100

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 18:13:58

Generated On: 09 Jun 2021 15:47:13

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

US3212100

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 18:13:58

Generated On: 09 Jun 2021 15:47:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212100

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

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

US3212100

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 18:13:58

Generated On: 09 Jun 2021 15:47:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212100

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3212100

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212100

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

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

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

Folder OID	VISIT3
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US3212100

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	06 OCT 2020
Time of assessment (00:00-23:59)	13:01 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 13:01
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212100

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 OCT 2020

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

US3212100

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 06 OCT 2020

Collection time (00:00-23:59) 13:49 (24 HR)

Collection date and time (derived) 06 OCT 2020 13:49

US3212100

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 OCT 2020 07:02:07
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

19 OCT 2020 23:10:08

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

24 OCT 2020 06:24:53

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 NOV 2020 17:13:51

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

14 NOV 2020 17:02:01

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	21 NOV 2020 06:26:07
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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	25 NOV 2020 17:02:30
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 DEC 2020 05:23:43
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 DEC 2020 05:54:49
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 <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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	16 DEC 2020 03:03:45
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2020 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 <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	30 DEC 2020 07:32:32
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

10 JAN 2021 19:44:37

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

13 JAN 2021 07:18:19

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

20 JAN 2021 03:27:55

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

28 JAN 2021 06:38:59

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 06:05:54

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

10 FEB 2021 06:10:53

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

18 FEB 2021 08:24:56

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

24 FEB 2021 06:36:30

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

03 MAR 2021 05:16:54

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

10 MAR 2021 06:04:08

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

17 MAR 2021 09:47:05

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

24 MAR 2021 09:55:44

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 MAR 2021 06:11:08
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 <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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	07 APR 2021 07:27:26
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	14 APR 2021 07:11:41
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

21 APR 2021 05:13:18

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

28 APR 2021 05:22:17

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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°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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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"/>

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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°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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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°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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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°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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
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Patient Cloud Close Date & Time	29 AUG 2021 23:59
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US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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"/>

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐
Yes ☐

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

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
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Patient Cloud Close Date & Time	26 SEP 2021 23:59
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US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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°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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	17 OCT 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	31 OCT 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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"/>

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

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16 JAN 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

Date and time of submission

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19 JAN 2022 00:01

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23 JAN 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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30 JAN 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212100

Folder: New Safety Follow Up Diary (1)

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

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06 FEB 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

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13 FEB 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

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20 FEB 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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 ☐

US3212100

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US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

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US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

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US3212100

Folder: New Safety Follow Up Diary (1)

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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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

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20 MAR 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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23 MAR 2022 00:01

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27 MAR 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

US3212100

Folder: New Safety Follow Up Diary (1)

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

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03 APR 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212100

Folder: New Safety Follow Up Diary (1)

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10 APR 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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"/>

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	14 AUG 2022 23:59
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US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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"/>

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	28 AUG 2022 23:59
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US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
Patient Cloud Close Date & Time	11 SEP 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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°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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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"/>

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	12 OCT 2022 00:01
Patient Cloud Close Date & Time	16 OCT 2022 23:59

US3212100

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:47:13

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 17:54:40

US3212100

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3212100

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 18:13:59

Generated On: 09 Jun 2021 15:47:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212100

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212100

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212100

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212100

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212100

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212100

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212100

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

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

Visit date (dd MMM yyyy)	09 MAR 2021
--------------------------	-------------

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

Folder OID	VISIT4
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US3212100

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 MAR 2021
Time of assessment (00:00-23:59)	12:22 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 12:22
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212100

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 MAR 2021

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

US3212100

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 MAR 2021
Collection time (00:00-23:59)	12:45 (24 HR)
Collection date and time (derived)	9 MAR 2021 12:45

US3212100

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212100

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212100

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212100

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 18:29:35

Generated On: 09 Jun 2021 15:47:13

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 MAY 2021

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

Comments

If Contact Not Made, please provide Comments

US3212100

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 18:29:35

Generated On: 09 Jun 2021 15:47:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212100

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

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

US3212100

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: COVID-19 Contact

Data signed: (b) (4) 16 Apr 2021 19:08:45

Generated On: 09 Jun 2021 15:47:13

Date of Contact	8 APR 2021
Time of Contact	13:30
Date and Time of Contact (derived)	8 APR 2021 13:30
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

Symptom Day

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

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	5 APR 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

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

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

Symptom Day

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

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

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

Date	6 APR 2021
------	------------

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

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

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

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

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

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

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

Symptom Day

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

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	7 APR 2021	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

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

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

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

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

Symptom Day

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

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	8 APR 2021	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

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

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

Nasal Congestion

None ☐
Mild ☐
Moderate ☒
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☐
Moderate ☒
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

Symptom Day

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

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 APR 2021	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

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

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

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

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (6)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

Symptom Day

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

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (6)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

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

Date	10 APR 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

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

Temperature	98.2 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (6)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (6)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

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

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (7)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

Symptom Day

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

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (7)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 APR 2021	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (7)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (7)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

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

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (8)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

Symptom Day

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

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (8)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 APR 2021	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (8)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

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

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (8)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

Symptom Day

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

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 APR 2021	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

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

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EAB) (1725)

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US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 16 Apr 2021 19:08:45

Generated On: 09 Jun 2021 15:47:13

Date of Visit	8 APR 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	8 APR 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 16 Apr 2021 19:08:45

Generated On: 09 Jun 2021 15:47:13

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3212100

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	10 APR 2021
Day 5	Yes	12 APR 2021
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3212100

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 19:08:46

Generated On: 09 Jun 2021 15:47:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3212100

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 19:08:46

Generated On: 09 Jun 2021 15:47:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 APR 2021
Time of assessment (00:00-23:59)	13:25 (24 HR)
Vital Signs Date and Time (derived)	8 APR 2021 13:25
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 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)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212100

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 19:08:46

Generated On: 09 Jun 2021 15:47:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 APR 2021

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

US3212100

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 16 Apr 2021 19:08:46

Generated On: 09 Jun 2021 15:47:13

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

8 APR 2021

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

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

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

Folder OID	SICKD28
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US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

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.

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 22 Apr 2021 19:26:28

Generated On: 09 Jun 2021 15:47:13

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3212100

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

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

Visit date (dd MMM yyyy)	02 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	UNBLND_DECIDE
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US3212100

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

Date of updated informed consent (*dd MMM yyyy*) 02 FEB 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*) 02 FEB 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 _____

US3212100

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 FEB 2021

Collection time (00:00-23:59)

08:46 (24 HR)

Collection date and time (derived)

02 FEB 2021 08:46

US3212100

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 FEB 2021
Collection time (00:00 - 23:59)	08:43
Collection Date and Time (derived)	02 FEB 2021 08:43

US3212100

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 31 Mar 2021 00:56:53

Generated On: 09 Jun 2021 15:47:13

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3212100

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 20 Apr 2021 18:37:35

Generated On: 09 Jun 2021 15:47:13

AEID

Adverse event

BRUISED INJECTION SITE

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)

16 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 AUG 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 (1)

Data signed: (b) (4) 20 Apr 2021 18:37:35

Generated On: 09 Jun 2021 15:47:13

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" 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	True
Concomitant Medication	False
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:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 20 Apr 2021 18:37:35

Generated On: 09 Jun 2021 15:47:13

AEID	
Adverse event	JAW PAIN
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	14 AUG 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)	29 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 20 Apr 2021 18:37:35

Generated On: 09 Jun 2021 15:47:13

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	True
Concomitant Medication	False
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:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 20 Apr 2021 18:37:35

Generated On: 09 Jun 2021 15:47:13

AEID

Adverse event

LOWER BACK 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)

14 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

01 SEP 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 (3)

Data signed: (b) (4) 20 Apr 2021 18:37:35

Generated On: 09 Jun 2021 15:47:13

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	True
Concomitant Medication	False
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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 20 Apr 2021 18:37:35

Generated On: 09 Jun 2021 15:47:13

AEID

Adverse event

SKIN RASH OF RIGHT BREAST

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)

16 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

20 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)

Data signed: (b) (4) 20 Apr 2021 18:37:35

Generated On: 09 Jun 2021 15:47:13

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: Adverse Events

Form: Adverse Events (6)

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AEID	USA-US115-2021-MRNA-1273-P30 1000001
Adverse event	PELVIC PAIN
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)	15 DEC 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)	27 DEC 2020
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 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)	15 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	17 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (6)

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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	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"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (6)

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SHE HAD A PLANNED
HYSTERECTOMY TO REMOVE
FIBROIDS. DURING THE
SURGERY, THE FIBROIDS WERE
EXTENSIVE, SO THE
FALLOPIAN TUBES WERE NOT
REMOVED. SHE REMAINED
HOSPITALIZED FOR 2 DAYS.
THE COMPLICATION OF
EXTENSIVE FIBROIDS MAY
HAVE PROLONGED THE
PLANNED HOSPITALIZATION.

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 (7)

Data signed: (b) (4) 20 Apr 2021 18:37:35

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AEID

Adverse event

INJECTION SITE 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)

10 AUG 2020

Start time (00:00-23:59)

15:41 (24 HR)

AE start date and time (derived)

10 AUG 2020 15:41

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

20 AUG 2020

End time (00:00-23:59)

12:11 (24 HR)

AE End Date and Time (derived)

20 AUG 2020 12:11

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 (7)

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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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" 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	True
Concomitant Medication	False
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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 20 Apr 2021 18:37:35

Generated On: 09 Jun 2021 15:47:13

AEID	
Adverse event	
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Start date (dd MMM yyyy)	
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="checkbox"/> No <input type="checkbox"/>
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="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input type="checkbox"/>
AE is serious due To (check all that apply)	
Death	
Life threatening	
Requires inpatient or prolongation of existing Hospitalization	
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 20 Apr 2021 18:37:35

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Persistent or significant disability or incapacity	
Congenital anomaly or birth defect	
Other medically important event	
Relationship to investigational product	Not Related <input type="checkbox"/>
	Related <input type="checkbox"/>
	Not Applicable <input type="checkbox"/>
Relationship to Study Procedure	Not Related <input type="checkbox"/>
	Related <input type="checkbox"/>
	Not Applicable <input type="checkbox"/>
Action taken with investigational product	None <input type="checkbox"/>
	Dose Delayed <input type="checkbox"/>
	Investigational Product <input type="checkbox"/>
	Withdrawn <input type="checkbox"/>
	Not Applicable <input type="checkbox"/>
Other action taken (check all that apply)	
None	
Concomitant Medication	
Concomitant Procedure	
Outcome	Fatal <input type="checkbox"/>
	Not Recovered/Not Resolved <input type="checkbox"/>
	Recovered/Resolved <input type="checkbox"/>
	Recovered/Resolved with <input type="checkbox"/>
	Sequelae <input type="checkbox"/>
	Recovering/Resolving <input type="checkbox"/>
	Unknown <input type="checkbox"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	
Medically Attended AE Derived (CSA Programming Field Only)	
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

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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) 02 Apr 2021 18:10:57

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Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication GLUCOSE INTOLERANCE

Dose per administration 500

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 2007	
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 (2)

Data signed: (b) (4) 02 Apr 2021 18:10:57

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Name of Medication MULIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication WELLNESS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

	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 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 (3)

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Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication PREVENTATIVE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 18:10:57

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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 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 18:10:57

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Name of Medication BCAA BRANCHED-CHAIN
AMINO ACID

Prophylaxis Yes ☒
No ☐

Indication MUSCLE BUILDING

Dose per administration UNK

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 (4)

Data signed: (b) (4) 02 Apr 2021 18:10:57

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	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 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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 18:10:57

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Name of Medication LO LOESTRIN

Prophylaxis Yes ☒
No ☐

Indication BIRTH CONTROL

Dose per administration 1 /10 /10

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

If dose unit is Other, specify MG/MCG/MCG

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 18:10:57

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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)	01 MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	10 DEC 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 (6)

Data signed: (b) (4) 02 Apr 2021 18:10:57

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Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIC
RHINITIS, FEVER/PAIN
REACTOGENICITY

Dose per administration 200-400

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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	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)		
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 (7)

Data signed: (b) (4) 02 Apr 2021 18:10:57

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Name of Medication CLINDAMYCIN

Prophylaxis Yes ☐
No ☒

Indication SKIN RASH OF RIGHT BREAST

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

	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)	17 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	28 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

Name of Medication HYDROCODONE-ACETAMINOP
HEN (NORCO)

Prophylaxis Yes ☐
No ☒

Indication PELVIC PAIN

Dose per administration 5-325

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

	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)	17 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication PELVIC PAIN

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

	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)		17 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3212100

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3212100

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
17 SEP 2020	PELVIC ULTRASOUND	Adverse Event	
1 DEC 2020	PELVIC ULTRASOUND	Medical History	
15 DEC 2020	TOTAL ABDOMINAL HYSTERECTOMY	Other	MEDICAL HISTORY ((LEIOMYOMA OF UTERUS) AND ADVERSE EVENT (PELVIC PAIN)

US3212100

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:47:13

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

US3212100

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:47:13

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 ☐

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

SAEID	USA-US115-2021-MRNA-1273-P301000001
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	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

SAEID	USA-US115-2021-MRNA-1273-P301000001
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	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	04/JAN/2021 17:12
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

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

SAEID	USA-US115-2021-MRNA-1273-P301000001
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	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	03/FEB/2021 11:43
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

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 18:10:57

Generated On: 09 Jun 2021 15:47:13

SAEID	USA-US115-2021-MRNA-1273-P301000001
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	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	26/MAR/2021 09:24
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

Audit

US3212100 (Prod: DM Clinical Research - ERN - PPDS)

US3212100

Form: Participant Creation

Generated On: 09 Jun 2021 15:47:13

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'US3212100'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 15:45:42

US3212100

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:48:56

US3212100

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 15:45:43

US3212100

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

[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 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Clinic (Clinic)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:48:56

US3212100

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered 'SCRN'	System	10 Aug 2020 15:48:56

US3212100

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered (b) (6) 1981'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 15:45:44

US3212100

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:47:13

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '38'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:49:08

US3212100

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:47:13

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered 'YEARS'	System	10 Aug 2020 15:49:08

US3212100

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:47:13

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered '38'	System	10 Aug 2020 15:49:19

US3212100

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:47:13

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Female (F)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:49:08

US3212100

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:47:13

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:49:08

US3212100

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:47:13

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'I'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:49:08

US3212100

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:47:13

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:49:08

US3212100

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:47:13

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:49:08

US3212100

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:47:13

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:49:08

US3212100

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:47:13

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:49:08

US3212100

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:47:13

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:49:08

US3212100

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:47:13

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:49:08

US3212100

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:47:13

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:49:08

US3212100

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:47:13

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:49:08

US3212100

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:47:13

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '10 Aug 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:49:19

US3212100

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered 'Aug 2020'	System	10 Aug 2020 15:49:19

US3212100

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered '2020'	System	10 Aug 2020 15:49:19

US3212100

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:47:13

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Amendment 2 (2)' reason for change: Data Entry Error	(b) (4) Heather Leary (b) (4)	11 Aug 2020 15:12:36
User entered 'Amendment 1 (1)'	(b) (4) Afifah Ayub (b) (4)	10 Aug 2020 15:49:19

US3212100

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:49:19

US3212100

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:49:19

US3212100

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:47:13

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:49:19

US3212100

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:47:13

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:49:19

US3212100

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:47:13

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 15:45:43

US3212100

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:47:13

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered 'I'	System	10 Aug 2020 15:49:31

US3212100

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:49:31

US3212100

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:47:13

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:49:41

US3212100

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:47:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Glucose tolerance impaired, LLT: Prediabetes - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	10 Aug 2020 15:51:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 15:51:17
Data point term sent to Coder	System	10 Aug 2020 15:50:28
User entered 'Prediabetes'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:50:02

US3212100

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'UN UNK 2007'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:50:02

US3212100

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:47:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:50:02

US3212100

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:47:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:50:02

US3212100

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:47:13

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:50:02

US3212100

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:47:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:50:02

US3212100

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered 'Jan 2007'	System	10 Aug 2020 15:50:02

US3212100

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered '2007'	System	10 Aug 2020 15:50:02

US3212100

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered empty.	System	10 Aug 2020 15:50:02

US3212100

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered empty.	System	10 Aug 2020 15:50:02

US3212100

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:47:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
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) (4), (b) (6)	16 Oct 2020 19:27:59
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 'updated and added' (Site from DM).	Afifah Ayub (b) (4) (b) (4)	16 Sep 2020 16:45:17
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)	10 Sep 2020 17:07:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 15:51:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 15:51:17
Data point term sent to Coder	System	10 Aug 2020 15:50:28
User entered 'Cholecystectomy'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:50:24

US3212100

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'UN UNK 2008'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:50:24

US3212100

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:47:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:50:24

US3212100

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:47:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:50:24

US3212100

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'UN UNK 2008'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:50:24

US3212100

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:47:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:50:24

US3212100

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered 'Jan 2008'	System	10 Aug 2020 15:50:24

US3212100

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered '2008'	System	10 Aug 2020 15:50:24

US3212100

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered 'Jan 2008'	System	10 Aug 2020 15:50:24

US3212100

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered '2008'	System	10 Aug 2020 15:50:24

US3212100

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:47:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	16 Sep 2020 16:45:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 16:45:45
Data point term sent to Coder	System	16 Sep 2020 16:44:51
User entered 'SEASONAL ALLERGIC RHINITIS'	Afifah Ayub (b) (4) (b) (4)	16 Sep 2020 16:44:50

US3212100

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'UN UNK 2000'	(b) (4) Afifah Ayub (b) (4) (b) (4)	16 Sep 2020 16:44:50

US3212100

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:47:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	16 Sep 2020 16:44:50

US3212100

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:47:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	16 Sep 2020 16:44:50

US3212100

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	16 Sep 2020 16:44:50

US3212100

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:47:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	16 Sep 2020 16:44:50

US3212100

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered 'Jan 2000'	System	16 Sep 2020 16:44:50

US3212100

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered '2000'	System	16 Sep 2020 16:44:50

US3212100

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered empty.	System	16 Sep 2020 16:44:50

US3212100

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered empty.	System	16 Sep 2020 16:44:50

US3212100

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:47:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	16 Sep 2020 16:46:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 16:46:40
Data point term sent to Coder	System	16 Sep 2020 16:45:52
User entered 'cholecystitis'	Afifah Ayub (b) (4) (b) (4)	16 Sep 2020 16:45:03

US3212100

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'UN UNK 2008'	(b) (4) Afifah Ayub (b) (4) (b) (4)	16 Sep 2020 16:45:03

US3212100

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:47:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	16 Sep 2020 16:45:03

US3212100

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:47:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	16 Sep 2020 16:45:03

US3212100

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'UN UNK 2008'	(b) (4) Afifah Ayub (b) (4) (b) (4)	16 Sep 2020 16:45:03

US3212100

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:47:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	16 Sep 2020 16:45:03

US3212100

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered 'Jan 2008'	System	16 Sep 2020 16:45:03

US3212100

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered '2008'	System	16 Sep 2020 16:45:03

US3212100

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered 'Jan 2008'	System	16 Sep 2020 16:45:03

US3212100

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered '2008'	System	16 Sep 2020 16:45:03

US3212100

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:47:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine leiomyoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 14:00:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 14:00:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
Data point term sent to Coder	System	25 Mar 2021 14:05:09
Coding entries removed.	Jagruti Patel (b) (4)	25 Mar 2021 14:04:46
	(b) (4)	
User entered 'Leiomyoma of Uterus' reason for change: Data Entry Error	Jagruti Patel (b) (4)	25 Mar 2021 14:04:46
	(b) (4)	
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:00:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:00:57
Data point term sent to Coder	System	07 Oct 2020 15:53:53
User entered 'Uterine fibroids'	Afifah Ayub (b) (4) (b) (4)	07 Oct 2020 15:53:10

US3212100

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Un UNK 2017'	(b) (4) Afifah Ayub (b) (4) (b) (4)	07 Oct 2020 15:53:10

US3212100

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:47:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	07 Oct 2020 15:53:10

US3212100

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:47:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	07 Oct 2020 15:53:10

US3212100

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	07 Oct 2020 15:53:10

US3212100

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:47:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	07 Oct 2020 15:53:10

US3212100

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered 'Jan 2017'	System	07 Oct 2020 15:53:10

US3212100

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered '2017'	System	07 Oct 2020 15:53:10

US3212100

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered empty.	System	07 Oct 2020 15:53:10

US3212100

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered empty.	System	07 Oct 2020 15:53:10

US3212100

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:57:17

US3212100

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '10 Aug 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:57:17

US3212100

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered '09:42' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Dec 2020 15:46:58
User entered '9:42'	Afifah Ayub (b) (4)	10 Aug 2020 15:57:17
	(b) (4)	

US3212100

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered '10 Aug 2020 09:42'	System	08 Dec 2020 15:46:58
User entered '10 Aug 2020 9:42'	System	10 Aug 2020 15:57:17

US3212100

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '62' in	(b) (4) Afifah Ayub (b) (4)	10 Aug 2020 15:57:17
DataPoint set to visible.	(b) (4) System	10 Aug 2020 15:49:31

US3212100

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '157' lb	(b) (4) Afifah Ayub (b) (4)	10 Aug 2020 15:57:17
DataPoint set to visible.	(b) (4) System	10 Aug 2020 15:49:31

US3212100

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
Amendment Manager: User entered '28.77572'	System	16 Sep 2020 23:49:52
User entered '28.8'	System	10 Aug 2020 15:57:17
DataPoint set to visible.	System	10 Aug 2020 15:49:31

US3212100

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered 'kg/m2'	System	10 Aug 2020 15:57:17
DataPoint set to visible.	System	10 Aug 2020 15:49:31

US3212100

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4)	21 Aug 2020 16:59:22
User entered '97.8' F	Afifah Ayub (b) (4)	10 Aug 2020 15:57:17
	(b) (4)	

US3212100

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty; reason for change Data Entry Error	(b) (4) Afifah Ayub (b) (4)	07 Oct 2020 17:22:58
User entered 'Other (Other)'	(b) (4) Afifah Ayub (b) (4)	10 Aug 2020 15:57:17

US3212100

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty; reason for change Data Entry Error	(b) (4) Afifah Ayub (b) (4)	07 Oct 2020 17:22:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Afifah Ayub (b) (4)	21 Aug 2020 16:59:22
User entered 'tempo'	(b) (4) Afifah Ayub (b) (4)	10 Aug 2020 15:57:17

US3212100

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4)	21 Aug 2020 16:59:22
User entered '77'	Afifah Ayub (b) (4)	10 Aug 2020 15:57:17
	(b) (4)	

US3212100

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered 'bpm'	System	10 Aug 2020 15:57:17

US3212100

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Aug 2020 16:59:22
User entered '14'	Afifah Ayub (b) (4)	10 Aug 2020 15:57:17

US3212100

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered 'breaths/min'	System	10 Aug 2020 15:57:17

US3212100

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4)	21 Aug 2020 16:59:22
User entered '133'	Afifah Ayub (b) (4)	10 Aug 2020 15:57:17
	(b) (4)	

US3212100

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered 'mmHg'	System	10 Aug 2020 15:57:17

US3212100

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4)	21 Aug 2020 16:59:22
User entered '84'	Afifah Ayub (b) (4)	10 Aug 2020 15:57:17
	(b) (4)	

US3212100

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered 'mmHg'	System	10 Aug 2020 15:57:17

US3212100

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33

US3212100

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33

US3212100

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:47:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:50:44

US3212100

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:47:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 08:17:37
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 19:10:00
User entered '10 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:50:44

US3212100

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:47:13

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '10 Aug 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:51:06

US3212100

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:47:13

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:51:06

US3212100

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:51:06

US3212100

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:51:06

US3212100

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:51:06

US3212100

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:47:13

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:51:06

US3212100

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:51:06

US3212100

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:47:13

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:51:06

US3212100

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:47:13

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:51:29

US3212100

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:47:13

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '10 Aug 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:51:29

US3212100

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:47:13

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Urine (URINE)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:51:29

US3212100

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:47:13

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Negative (NEGATIVE)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:51:29

US3212100

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:47:13

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:51:29

US3212100

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:47:13

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:51:29

US3212100

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:47:13

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:51:29

US3212100

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User entered empty.	System	10 Aug 2020 15:51:29

US3212100

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:47:13

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 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:05

US3212100

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:47:13

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 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:05

US3212100

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:47:13

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 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:05

US3212100

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:47:13

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 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:05

US3212100

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:47:13

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 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:05

US3212100

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:47:13

[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 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:05

US3212100

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:47:13

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 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:05

US3212100

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:47:13

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 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:05

US3212100

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:47:13

[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 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:05

US3212100

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:47:13

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 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:05

US3212100

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:47:13

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 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:05

US3212100

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:47:13

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:05

US3212100

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:47:13

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'College Professor'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:05

US3212100

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:47:13

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:05

US3212100

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:47:13

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:05

US3212100

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:05

US3212100

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:47:13

[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 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:05

US3212100

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:47:13

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 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:05

US3212100

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:05

US3212100

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:47:13

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'I'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:05

US3212100

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:47:13

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:28:33
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'People in the participant's workplace are not regularly using personal protection equipment. Participant goes in person to their main workplace more than 2 days/week...'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:05

US3212100

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:17

US3212100

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '10 Aug 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:17

US3212100

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

[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 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Clinic (Clinic)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:17

US3212100

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'VISIT1'	System	10 Aug 2020 15:58:17

US3212100

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 15:49:27

US3212100

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:47:13

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:16:58
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:16:57
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 15:49:27
User entered '102571' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 15:49:27

US3212100

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 15:49:27

US3212100

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:47:13

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 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:51

US3212100

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:47:13

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 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:51

US3212100

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:51

US3212100

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:51

US3212100

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:47:13

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:58:51

US3212100

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4)	07 Oct 2020 15:54:20
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:04:36
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:46:06

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:47:13

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered missing code ND - Not Done.	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:47:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered missing code ND - Not Done.	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:47:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered missing code ND - Not Done.	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:47:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered missing code ND - Not Done.	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User accepted default value 'Pre-Dose (PREDOSE)'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '10 Aug 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered '09:42' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Dec 2020 15:47:23
User entered '9:42'	Afifah Ayub (b) (4)	10 Aug 2020 21:10:22
	(b) (4)	

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered '10 Aug 2020 09:42'	System	08 Dec 2020 15:47:23
User entered '10 Aug 2020 9:42'	System	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '97.8' F	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Other (Other)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'tempo'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '77'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'bpm'	System	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '14'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'breaths/min'	System	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '133'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'mmHg'	System	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '84'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'mmHg'	System	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:47:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered missing code ND - Not Done.	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:47:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered missing code ND - Not Done.	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User accepted default value 'Post-Dose (POSTDOSE)'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '10 Aug 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
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)	12 Aug 2020 13:17:49
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)	10 Aug 2020 21:10:39
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	10 Aug 2020 21:10:22
User entered '11:58'	Afifah Ayub (b) (4)	10 Aug 2020 21:10:22
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered '10 Aug 2020 11:58'	System	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '99.1' F	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Oral (Oral)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '78'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'bpm'	System	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '15'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'breaths/min'	System	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '124'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'mmHg'	System	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '72'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'mmHg'	System	10 Aug 2020 21:10:22

US3212100

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:47:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	21 Aug 2020 16:59:53
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	10 Aug 2020 15:59:00
	(b) (4)	

US3212100

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:47:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	21 Aug 2020 16:59:53
	(b) (4)	
User entered '10 Aug 2020'	Afifah Ayub (b) (4)	10 Aug 2020 15:59:00
	(b) (4)	

US3212100

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:47:13

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	21 Aug 2020 17:00:14
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	10 Aug 2020 15:59:17
	(b) (4)	

US3212100

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:47:13

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty; reason for change Data Entry Error	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Aug 2020 17:00:14
User entered '10 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:59:17

US3212100

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:47:13

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	21 Aug 2020 17:00:14
	(b) (4)	
User entered 'Urine (URINE)'	Afifah Ayub (b) (4)	10 Aug 2020 15:59:17
	(b) (4)	

US3212100

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:47:13

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	21 Aug 2020 17:00:14
User entered 'Negative (NEGATIVE)'	Afifah Ayub (b) (4)	10 Aug 2020 15:59:17
	(b) (4)	

US3212100

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:47:13

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	20 Oct 2020 17:00:51
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	21 Aug 2020 17:00:14
User entered 'No (N)'	Afifah Ayub (b) (4)	10 Aug 2020 15:59:17

US3212100

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:47:13

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:59:17

US3212100

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:47:13

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:59:17

US3212100

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered empty.	System	10 Aug 2020 15:59:17

US3212100

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:47:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 16:31:34

US3212100

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:47:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 16:31:34

US3212100

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:47:13

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 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 16:31:34

US3212100

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:47:13

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 16:31:34

US3212100

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '10 Aug 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 16:31:34

US3212100

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '11:28'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 16:31:34

US3212100

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered '10 Aug 2020 11:28'	System	10 Aug 2020 16:31:34

US3212100

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Left Arm (LEFT ARM)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 16:31:34

US3212100

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'ONCE'	System	10 Aug 2020 16:31:34

US3212100

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 16:31:34

US3212100

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:47:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 16:31:49

US3212100

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:47:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '10 Aug 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 16:31:49

US3212100

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '11:09'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 16:31:49

US3212100

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered '10 Aug 2020 11:09'	System	10 Aug 2020 16:31:49

US3212100

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:47:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '10 Aug 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 16:32:07

US3212100

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:47:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 16:32:07

US3212100

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:47:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 16:32:07

US3212100

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '11:04'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 16:32:07

US3212100

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered '10 Aug 2020 11:04'	System	10 Aug 2020 16:32:07

US3212100

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:47:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 16:32:07

US3212100

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:47:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Aug 2020 20:32:52
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	10 Aug 2020 16:32:07
	(b) (4)	

US3212100

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:47:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Aug 2020 20:32:52
User entered '11:04'	Afifah Ayub (b) (4)	10 Aug 2020 16:32:07
	(b) (4)	

US3212100

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered empty.	System	25 Aug 2020 20:32:52
User entered '10 Aug 2020 11:04'	System	10 Aug 2020 16:32:07

US3212100

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	18 Aug 2020 20:08:33

US3212100

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'I'	System	18 Aug 2020 20:08:33

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T11:55:48', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'e3f933e9-566f-40f5-a1ce-2537dfb31880'	System	10 Aug 2020 16:56:05
User entered 'Yes (Y)'	System	10 Aug 2020 16:56:05

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T11:55:52', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'e3f933e9-566f-40f5-a1ce-2537dfb31880'	System	10 Aug 2020 16:56:05
User entered '99.1'	System	10 Aug 2020 16:56:05

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T11:55:56', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'e3f933e9-566f-40f5-a1ce-2537dfb31880'	System	10 Aug 2020 16:56:05
User entered 'No (N)'	System	10 Aug 2020 16:56:05

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T11:56:03', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'e3f933e9-566f-40f5-a1ce-2537dfb31880'	System	10 Aug 2020 16:56:05
User entered '10 Aug 2020 11:56'	System	10 Aug 2020 16:56:05

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '10 Aug 2020 11:48'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '10 Aug 2020 14:18'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T15:41:11', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b5059bec-369d-43d6-a881-1a857c81107d'	System	10 Aug 2020 20:41:27
User entered 'Yes (Y)'	System	10 Aug 2020 20:41:27

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T15:41:14', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b5059bec-369d-43d6-a881-1a857c81107d' User entered '99.0'	System	10 Aug 2020 20:41:27
	System	10 Aug 2020 20:41:27

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T15:41:19', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b5059bec-369d-43d6-a881-1a857c81107d'	System	10 Aug 2020 20:41:27
User entered 'No (N)'	System	10 Aug 2020 20:41:27

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T15:41:24', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b5059bec-369d-43d6-a881-1a857c81107d'	System	10 Aug 2020 20:41:27
User entered '10 Aug 2020 15:41'	System	10 Aug 2020 20:41:27

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '10 Aug 2020 15:13'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 2'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:47:13

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-11T14:05:05', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '15d74b9f-b37d-46e4-8765-c8974652750f'	System	11 Aug 2020 19:05:15
User entered 'Yes (Y)'	System	11 Aug 2020 19:05:15

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:47:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-11T14:05:08', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '15d74b9f-b37d-46e4-8765-c8974652750f' User entered '99.2'	System	11 Aug 2020 19:05:15
	System	11 Aug 2020 19:05:15

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-11T14:05:11', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '15d74b9f-b37d-46e4-8765-c8974652750f'	System	11 Aug 2020 19:05:15
User entered 'No (N)'	System	11 Aug 2020 19:05:15

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-11T14:05:14', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '15d74b9f-b37d-46e4-8765-c8974652750f'	System	11 Aug 2020 19:05:15
User entered '11 Aug 2020 14:05'	System	11 Aug 2020 19:05:15

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 3'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:47:13

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-12T14:58:38', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '8bc7624a-9a87-4829-9ef5-c16c0de0160d'	System	12 Aug 2020 19:58:50
User entered 'Yes (Y)'	System	12 Aug 2020 19:58:50

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:47:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-12T14:58:42', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '8bc7624a-9a87-4829-9ef5-c16c0de0160d' User entered '99.4'	System	12 Aug 2020 19:58:50
	System	12 Aug 2020 19:58:50

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-12T14:58:47', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '8bc7624a-9a87-4829-9ef5-c16c0de0160d'	System	12 Aug 2020 19:58:50
User entered 'No (N)'	System	12 Aug 2020 19:58:50

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-12T14:58:49', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '8bc7624a-9a87-4829-9ef5-c16c0de0160d'	System	12 Aug 2020 19:58:50
User entered '12 Aug 2020 14:58'	System	12 Aug 2020 19:58:50

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 4'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:47:13

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-13T13:02:29', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '7e8dbee7-6da9-4231-a022-2495fadfcb58'	System	13 Aug 2020 18:02:55
User entered 'Yes (Y)'	System	13 Aug 2020 18:02:55

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:47:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-13T13:02:32', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '7e8dbee7-6da9-4231-a022-2495fadfcb58'	System	13 Aug 2020 18:02:55
User entered '98.8'	System	13 Aug 2020 18:02:55

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-13T13:02:46', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '7e8dbee7-6da9-4231-a022-2495fadfcb58'	System	13 Aug 2020 18:02:55
User entered 'No (N)'	System	13 Aug 2020 18:02:55

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-13T13:02:51', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '7e8dbee7-6da9-4231-a022-2495fadfcb58'	System	13 Aug 2020 18:02:55
User entered '13 Aug 2020 13:02'	System	13 Aug 2020 18:02:55

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 5'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:47:13

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-14T15:41:33', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '63d3fd5b-c2ef-426f-be80-7ccc57ffb3b8'	System	14 Aug 2020 20:41:58
User entered 'Yes (Y)'	System	14 Aug 2020 20:41:58

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:47:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-14T15:41:39', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '63d3fd5b-c2ef-426f-be80-7ccc57ffb3b8'	System	14 Aug 2020 20:41:58
User entered '99.0'	System	14 Aug 2020 20:41:58

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-14T15:41:41', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '63d3fd5b-c2ef-426f-be80-7ccc57ffb3b8'	System	14 Aug 2020 20:41:58
User entered 'No (N)'	System	14 Aug 2020 20:41:58

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-14T15:41:45', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '63d3fd5b-c2ef-426f-be80-7ccc57ffb3b8'	System	14 Aug 2020 20:41:58
User entered '14 Aug 2020 15:41'	System	14 Aug 2020 20:41:58

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 6'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:47:13

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-15T13:00:50', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '1e406861-0104-480e-a472-ad2cab4f3a9'	System	15 Aug 2020 18:01:02
User entered 'Yes (Y)'	System	15 Aug 2020 18:01:02

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:47:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-15T13:00:54', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '1e406861-0104-480e-a472-ad2cab4f3a9'	System	15 Aug 2020 18:01:02
User entered '99.2'	System	15 Aug 2020 18:01:02

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-15T13:00:58', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '1e406861-0104-480e-a472-ad2cab4f3a9'	System	15 Aug 2020 18:01:02
User entered 'No (N)'	System	15 Aug 2020 18:01:02

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-15T13:01:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '1e406861-0104-480e-a472-ad2cab4f3a9'	System	15 Aug 2020 18:01:02
User entered '15 Aug 2020 13:01'	System	15 Aug 2020 18:01:02

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 7'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:47:13

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-16T15:55:19', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '78e7c84b-22d4-4f7d-897f-5af93422a5ea'	System	16 Aug 2020 20:55:42
User entered 'Yes (Y)'	System	16 Aug 2020 20:55:42

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:47:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-16T15:55:23', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '78e7c84b-22d4-4f7d-897f-5af93422a5ea'	System	16 Aug 2020 20:55:42
User entered '98.0'	System	16 Aug 2020 20:55:42

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-16T15:55:32', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '78e7c84b-22d4-4f7d-897f-5af93422a5ea'	System	16 Aug 2020 20:55:42
User entered 'Yes (Y)'	System	16 Aug 2020 20:55:42

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
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 'Conmeds updated' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 09:19:56
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 (7a4408d64bb91427)', Time: '2020-08-16T15:55:38', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '78e7c84b-22d4-4f7d-897f-5af93422a5ea'	Heather Leary (b) (4)	17 Aug 2020 21:39:03
User entered '1'	System	16 Aug 2020 20:55:42

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:47:13

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-16T15:55:38', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '78e7c84b-22d4-4f7d-897f-5af93422a5ea'	System	16 Aug 2020 20:55:42
User entered '0'	System	16 Aug 2020 20:55:42

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-16T15:55:41', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '78e7c84b-22d4-4f7d-897f-5af93422a5ea'	System	16 Aug 2020 20:55:42
User entered '16 Aug 2020 15:55'	System	16 Aug 2020 20:55:42

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	16 Aug 2020 20:55:42
User entered 'Day 8'	System	16 Aug 2020 20:55:42

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:47:13

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-17T14:43:57', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '5ba51bac-b281-453a-b2c4-e18eac3fad74'	System	17 Aug 2020 19:44:13
User entered 'Yes (Y)'	System	17 Aug 2020 19:44:13

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:47:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-17T14:44:02', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '5ba51bac-b281-453a-b2c4-e18eac3fad74' User entered '98.9'	System	17 Aug 2020 19:44:13
	System	17 Aug 2020 19:44:13

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-17T14:44:09', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '5ba51bac-b281-453a-b2c4-e18eac3fad74'	System	17 Aug 2020 19:44:13
User entered 'No (N)'	System	17 Aug 2020 19:44:13

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-17T14:44:12', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '5ba51bac-b281-453a-b2c4-e18eac3fad74'	System	17 Aug 2020 19:44:13
User entered '17 Aug 2020 14:44'	System	17 Aug 2020 19:44:13

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 20:55:42

US3212100

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 20:55:42

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T11:56:47', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bbbcd96e-e55a-4437-b43d-f59607fa77c1'	System	10 Aug 2020 16:57:35
User entered 'None (1)'	System	10 Aug 2020 16:57:35

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T11:57:10', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bbbcd96e-e55a-4437-b43d-f59607fa77c1'	System	10 Aug 2020 16:57:35
User entered 'No (N)'	System	10 Aug 2020 16:57:35

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T11:57:18', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bbbcd96e-e55a-4437-b43d-f59607fa77c1'	System	10 Aug 2020 16:57:35
User entered 'No (N)'	System	10 Aug 2020 16:57:35

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T11:57:28', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bbbcd96e-e55a-4437-b43d-f59607fa77c1'	System	10 Aug 2020 16:57:35
User entered 'None (1)'	System	10 Aug 2020 16:57:35

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T11:57:31', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bbbcd96e-e55a-4437-b43d-f59607fa77c1'	System	10 Aug 2020 16:57:35
User entered '10 Aug 2020 11:57'	System	10 Aug 2020 16:57:35

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '10 Aug 2020 11:48'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '10 Aug 2020 14:18'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T15:41:35', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '2e7e7b71-c164-4686-95b8-71ea83ae8f78'	System	10 Aug 2020 20:41:53
User entered 'Does not interfere with activity (2)'	System	10 Aug 2020 20:41:53

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T15:41:38', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '2e7e7b71-c164-4686-95b8-71ea83ae8f78'	System	10 Aug 2020 20:41:53
User entered 'No (N)'	System	10 Aug 2020 20:41:53

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T15:41:43', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '2e7e7b71-c164-4686-95b8-71ea83ae8f78'	System	10 Aug 2020 20:41:53
User entered 'No (N)'	System	10 Aug 2020 20:41:53

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T15:41:49', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '2e7e7b71-c164-4686-95b8-71ea83ae8f78'	System	10 Aug 2020 20:41:53
User entered 'None (1)'	System	10 Aug 2020 20:41:53

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T15:41:51', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '2e7e7b71-c164-4686-95b8-71ea83ae8f78'	System	10 Aug 2020 20:41:53
User entered '10 Aug 2020 15:41'	System	10 Aug 2020 20:41:53

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '10 Aug 2020 15:13'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 2'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-11T14:04:41', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0fd10a9a-a74d-46fe-921b-f903dc2cbc9b'	System	11 Aug 2020 19:05:01
User entered 'Does not interfere with activity (2)'	System	11 Aug 2020 19:05:01

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:47:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-11T14:04:47', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0fd10a9a-a74d-46fe-921b-f903dc2cbc9b'	System	11 Aug 2020 19:05:01
User entered 'No (N)'	System	11 Aug 2020 19:05:01

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-11T14:04:49', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0fd10a9a-a74d-46fe-921b-f903dc2cbc9b'	System	11 Aug 2020 19:05:01
User entered 'No (N)'	System	11 Aug 2020 19:05:01

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-11T14:04:55', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0fd10a9a-a74d-46fe-921b-f903dc2cbc9b'	System	11 Aug 2020 19:05:01
User entered 'None (1)'	System	11 Aug 2020 19:05:01

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-11T14:04:59', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0fd10a9a-a74d-46fe-921b-f903dc2cbc9b'	System	11 Aug 2020 19:05:01
User entered '11 Aug 2020 14:04'	System	11 Aug 2020 19:05:01

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 3'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-12T14:57:33', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '7cf23325-28a0-4bba-9923-4c61a02bd155'	System	12 Aug 2020 19:57:50
User entered 'None (1)'	System	12 Aug 2020 19:57:50

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-12T14:57:37', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '7cf23325-28a0-4bba-9923-4c61a02bd155'	System	12 Aug 2020 19:57:50
User entered 'No (N)'	System	12 Aug 2020 19:57:50

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-12T14:57:40', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '7cf23325-28a0-4bba-9923-4c61a02bd155'	System	12 Aug 2020 19:57:50
User entered 'No (N)'	System	12 Aug 2020 19:57:50

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-12T14:57:43', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '7cf23325-28a0-4bba-9923-4c61a02bd155'	System	12 Aug 2020 19:57:50
User entered 'None (1)'	System	12 Aug 2020 19:57:50

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-12T14:57:45', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '7cf23325-28a0-4bba-9923-4c61a02bd155'	System	12 Aug 2020 19:57:50
User entered '12 Aug 2020 14:57'	System	12 Aug 2020 19:57:50

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 4'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-13T13:03:01', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'c7953ff9-ca87-4adb-ba5b-005d77ad6341'	System	13 Aug 2020 18:03:16
User entered 'None (1)'	System	13 Aug 2020 18:03:16

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-13T13:03:04', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'c7953ff9-ca87-4adb-ba5b-005d77ad6341'	System	13 Aug 2020 18:03:16
User entered 'No (N)'	System	13 Aug 2020 18:03:16

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-13T13:03:08', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'c7953ff9-ca87-4adb-ba5b-005d77ad6341'	System	13 Aug 2020 18:03:16
User entered 'No (N)'	System	13 Aug 2020 18:03:16

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-13T13:03:11', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'c7953ff9-ca87-4adb-ba5b-005d77ad6341'	System	13 Aug 2020 18:03:16
User entered 'None (1)'	System	13 Aug 2020 18:03:16

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-13T13:03:13', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'c7953ff9-ca87-4adb-ba5b-005d77ad6341'	System	13 Aug 2020 18:03:16
User entered '13 Aug 2020 13:03'	System	13 Aug 2020 18:03:16

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 5'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-14T15:41:54', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bd9d0842-8800-41e1-81dd-8e96e5fdbb4b'	System	14 Aug 2020 20:42:10
User entered 'None (1)'	System	14 Aug 2020 20:42:10

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-14T15:41:57', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bd9d0842-8800-41e1-81dd-8e96e5fdbb4b'	System	14 Aug 2020 20:42:10
User entered 'No (N)'	System	14 Aug 2020 20:42:10

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-14T15:42:01', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bd9d0842-8800-41e1-81dd-8e96e5fdbb4b'	System	14 Aug 2020 20:42:10
User entered 'No (N)'	System	14 Aug 2020 20:42:10

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-14T15:42:05', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bd9d0842-8800-41e1-81dd-8e96e5fdbb4b'	System	14 Aug 2020 20:42:10
User entered 'None (1)'	System	14 Aug 2020 20:42:10

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-14T15:42:06', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bd9d0842-8800-41e1-81dd-8e96e5fdbb4b'	System	14 Aug 2020 20:42:10
User entered '14 Aug 2020 15:42'	System	14 Aug 2020 20:42:10

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 6'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-15T13:00:31', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '71f0bb41-ad7c-4c31-a763-ae45ff2abeaa'	System	15 Aug 2020 18:00:47
User entered 'None (1)'	System	15 Aug 2020 18:00:47

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-15T13:00:35', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '71f0bb41-ad7c-4c31-a763-ae45ff2abeaa'	System	15 Aug 2020 18:00:47
User entered 'No (N)'	System	15 Aug 2020 18:00:47

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-15T13:00:37', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '71f0bb41-ad7c-4c31-a763-ae45ff2abeaa'	System	15 Aug 2020 18:00:47
User entered 'No (N)'	System	15 Aug 2020 18:00:47

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-15T13:00:43', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '71f0bb41-ad7c-4c31-a763-ae45ff2abeaa'	System	15 Aug 2020 18:00:47
User entered 'None (1)'	System	15 Aug 2020 18:00:47

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-15T13:00:45', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '71f0bb41-ad7c-4c31-a763-ae45ff2abeaa'	System	15 Aug 2020 18:00:47
User entered '15 Aug 2020 13:00'	System	15 Aug 2020 18:00:47

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 7'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-16T15:55:57', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '087f9d63-cafe-4142-8053-da15e204247c'	System	16 Aug 2020 20:56:31
User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 20:56:31

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-16T15:56:13', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '087f9d63-cafe-4142-8053-da15e204247c'	System	16 Aug 2020 20:56:31
User entered 'No (N)'	System	16 Aug 2020 20:56:31

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-16T15:56:21', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '087f9d63-cafe-4142-8053-da15e204247c'	System	16 Aug 2020 20:56:31
User entered 'No (N)'	System	16 Aug 2020 20:56:31

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-16T15:56:26', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '087f9d63-cafe-4142-8053-da15e204247c'	System	16 Aug 2020 20:56:31
User entered 'None (1)'	System	16 Aug 2020 20:56:31

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-16T15:56:29', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '087f9d63-cafe-4142-8053-da15e204247c'	System	16 Aug 2020 20:56:31
User entered '16 Aug 2020 15:56'	System	16 Aug 2020 20:56:31

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T11:57:35', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'dc4d0dbd-5de0-4c62-93c1-17b913d6c05c'	System	10 Aug 2020 16:58:15
User entered 'None (0)'	System	10 Aug 2020 16:58:15

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T11:57:38', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'dc4d0dbd-5de0-4c62-93c1-17b913d6c05c'	System	10 Aug 2020 16:58:15
User entered 'None (0)'	System	10 Aug 2020 16:58:15

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T11:57:40', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'dc4d0dbd-5de0-4c62-93c1-17b913d6c05c'	System	10 Aug 2020 16:58:15
User entered 'None (0)'	System	10 Aug 2020 16:58:15

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T11:57:43', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'dc4d0dbd-5de0-4c62-93c1-17b913d6c05c'	System	10 Aug 2020 16:58:15
User entered 'None (0)'	System	10 Aug 2020 16:58:15

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T11:57:45', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'dc4d0dbd-5de0-4c62-93c1-17b913d6c05c'	System	10 Aug 2020 16:58:15
User entered 'None (0)'	System	10 Aug 2020 16:58:15

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T11:58:01', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'dc4d0dbd-5de0-4c62-93c1-17b913d6c05c'	System	10 Aug 2020 16:58:15
User entered 'No interference with activity (1)'	System	10 Aug 2020 16:58:15

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T11:58:12', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'dc4d0dbd-5de0-4c62-93c1-17b913d6c05c'	System	10 Aug 2020 16:58:15
User entered 'No (N)'	System	10 Aug 2020 16:58:15

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T11:58:15', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'dc4d0dbd-5de0-4c62-93c1-17b913d6c05c'	System	10 Aug 2020 16:58:15
User entered '10 Aug 2020 11:58'	System	10 Aug 2020 16:58:15

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '10 Aug 2020 11:48'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '10 Aug 2020 14:18'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T15:41:57', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'aee47b51-a5b2-48b9-a244-7de1715133c7'	System	10 Aug 2020 20:42:20
User entered 'None (0)'	System	10 Aug 2020 20:42:20

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T15:41:59', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'aee47b51-a5b2-48b9-a244-7de1715133c7'	System	10 Aug 2020 20:42:20
User entered 'None (0)'	System	10 Aug 2020 20:42:20

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T15:42:02', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'aee47b51-a5b2-48b9-a244-7de1715133c7'	System	10 Aug 2020 20:42:20
User entered 'None (0)'	System	10 Aug 2020 20:42:20

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T15:42:05', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'aee47b51-a5b2-48b9-a244-7de1715133c7'	System	10 Aug 2020 20:42:20
User entered 'None (0)'	System	10 Aug 2020 20:42:20

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T15:42:07', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'aee47b51-a5b2-48b9-a244-7de1715133c7'	System	10 Aug 2020 20:42:20
User entered 'None (0)'	System	10 Aug 2020 20:42:20

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T15:42:09', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'aee47b51-a5b2-48b9-a244-7de1715133c7'	System	10 Aug 2020 20:42:20
User entered 'None (0)'	System	10 Aug 2020 20:42:20

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T15:42:15', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'aee47b51-a5b2-48b9-a244-7de1715133c7'	System	10 Aug 2020 20:42:20
User entered 'No (N)'	System	10 Aug 2020 20:42:20

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-10T15:42:17', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'aee47b51-a5b2-48b9-a244-7de1715133c7'	System	10 Aug 2020 20:42:20
User entered '10 Aug 2020 15:42'	System	10 Aug 2020 20:42:20

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '10 Aug 2020 15:13'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 2'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-11T14:05:19', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'e3b316a7-e722-488d-8970-9684085708bd' User entered 'None (0)'	System	11 Aug 2020 19:05:44
	System	11 Aug 2020 19:05:44

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-11T14:05:23', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'e3b316a7-e722-488d-8970-9684085708bd'	System	11 Aug 2020 19:05:44
User entered 'None (0)'	System	11 Aug 2020 19:05:44

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-11T14:05:26', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'e3b316a7-e722-488d-8970-9684085708bd' User entered 'None (0)'	System	11 Aug 2020 19:05:44
	System	11 Aug 2020 19:05:44

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-11T14:05:28', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'e3b316a7-e722-488d-8970-9684085708bd' User entered 'None (0)'	System	11 Aug 2020 19:05:44
	System	11 Aug 2020 19:05:44

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-11T14:05:30', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'e3b316a7-e722-488d-8970-9684085708bd'	System	11 Aug 2020 19:05:44
User entered 'None (0)'	System	11 Aug 2020 19:05:44

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-11T14:05:32', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'e3b316a7-e722-488d-8970-9684085708bd'	System	11 Aug 2020 19:05:44
User entered 'None (0)'	System	11 Aug 2020 19:05:44

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-11T14:05:38', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'e3b316a7-e722-488d-8970-9684085708bd'	System	11 Aug 2020 19:05:44
User entered 'No (N)'	System	11 Aug 2020 19:05:44

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-11T14:05:40', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'e3b316a7-e722-488d-8970-9684085708bd'	System	11 Aug 2020 19:05:44
User entered '11 Aug 2020 14:05'	System	11 Aug 2020 19:05:44

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 3'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-12T14:57:57', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'd2a09493-5099-4f2e-b56a-5d0e3ba9626f'	System	12 Aug 2020 19:58:34
User entered 'None (0)'	System	12 Aug 2020 19:58:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-12T14:57:59', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'd2a09493-5099-4f2e-b56a-5d0e3ba9626f' User entered 'None (0)'	System	12 Aug 2020 19:58:34
	System	12 Aug 2020 19:58:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-12T14:58:10', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'd2a09493-5099-4f2e-b56a-5d0e3ba9626f'	System	12 Aug 2020 19:58:34
User entered 'None (0)'	System	12 Aug 2020 19:58:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-12T14:58:12', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'd2a09493-5099-4f2e-b56a-5d0e3ba9626f' User entered 'None (0)'	System	12 Aug 2020 19:58:34
	System	12 Aug 2020 19:58:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-12T14:58:15', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'd2a09493-5099-4f2e-b56a-5d0e3ba9626f'	System	12 Aug 2020 19:58:34
User entered 'None (0)'	System	12 Aug 2020 19:58:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-12T14:58:17', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'd2a09493-5099-4f2e-b56a-5d0e3ba9626f'	System	12 Aug 2020 19:58:34
User entered 'None (0)'	System	12 Aug 2020 19:58:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-12T14:58:32', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'd2a09493-5099-4f2e-b56a-5d0e3ba9626f'	System	12 Aug 2020 19:58:34
User entered 'No (N)'	System	12 Aug 2020 19:58:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-12T14:58:33', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'd2a09493-5099-4f2e-b56a-5d0e3ba9626f'	System	12 Aug 2020 19:58:34
User entered '12 Aug 2020 14:58'	System	12 Aug 2020 19:58:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 4'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-13T13:03:18', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'af316c7e-6dbe-450f-b1d2-cc9854b7f341'	System	13 Aug 2020 18:03:42
User entered 'None (0)'	System	13 Aug 2020 18:03:42

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-13T13:03:20', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'af316c7e-6dbe-450f-b1d2-cc9854b7f341'	System	13 Aug 2020 18:03:42
User entered 'None (0)'	System	13 Aug 2020 18:03:42

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-13T13:03:23', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'af316c7e-6dbe-450f-b1d2-cc9854b7f341'	System	13 Aug 2020 18:03:42
User entered 'None (0)'	System	13 Aug 2020 18:03:42

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-13T13:03:24', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'af316c7e-6dbe-450f-b1d2-cc9854b7f341'	System	13 Aug 2020 18:03:42
User entered 'None (0)'	System	13 Aug 2020 18:03:42

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-13T13:03:27', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'af316c7e-6dbe-450f-b1d2-cc9854b7f341'	System	13 Aug 2020 18:03:42
User entered 'None (0)'	System	13 Aug 2020 18:03:42

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-13T13:03:29', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'af316c7e-6dbe-450f-b1d2-cc9854b7f341'	System	13 Aug 2020 18:03:42
User entered 'None (0)'	System	13 Aug 2020 18:03:42

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-13T13:03:35', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'af316c7e-6dbe-450f-b1d2-cc9854b7f341'	System	13 Aug 2020 18:03:42
User entered 'No (N)'	System	13 Aug 2020 18:03:42

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-13T13:03:37', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'af316c7e-6dbe-450f-b1d2-cc9854b7f341'	System	13 Aug 2020 18:03:42
User entered '13 Aug 2020 13:03'	System	13 Aug 2020 18:03:42

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 5'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-14T15:42:10', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bfcc4c70-454e-42cd-a7fe-e9738b3d9d62'	System	14 Aug 2020 20:42:34
User entered 'None (0)'	System	14 Aug 2020 20:42:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-14T15:42:15', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bfcc4c70-454e-42cd-a7fe-e9738b3d9d62'	System	14 Aug 2020 20:42:34
User entered 'None (0)'	System	14 Aug 2020 20:42:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-14T15:42:17', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bfcc4c70-454e-42cd-a7fe-e9738b3d9d62'	System	14 Aug 2020 20:42:34
User entered 'None (0)'	System	14 Aug 2020 20:42:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-14T15:42:19', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bfcc4c70-454e-42cd-a7fe-e9738b3d9d62'	System	14 Aug 2020 20:42:34
User entered 'None (0)'	System	14 Aug 2020 20:42:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-14T15:42:21', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bfcc4c70-454e-42cd-a7fe-e9738b3d9d62'	System	14 Aug 2020 20:42:34
User entered 'None (0)'	System	14 Aug 2020 20:42:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-14T15:42:23', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bfcc4c70-454e-42cd-a7fe-e9738b3d9d62'	System	14 Aug 2020 20:42:34
User entered 'None (0)'	System	14 Aug 2020 20:42:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-14T15:42:28', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bfcc4c70-454e-42cd-a7fe-e9738b3d9d62'	System	14 Aug 2020 20:42:34
User entered 'No (N)'	System	14 Aug 2020 20:42:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-14T15:42:29', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bfcc4c70-454e-42cd-a7fe-e9738b3d9d62'	System	14 Aug 2020 20:42:34
User entered '14 Aug 2020 15:42'	System	14 Aug 2020 20:42:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 6'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-15T13:01:04', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '26481b1a-c65b-4cfc-bcd1-2c67d63d65eb'	System	15 Aug 2020 18:01:23
User entered 'None (0)'	System	15 Aug 2020 18:01:23

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-15T13:01:06', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '26481b1a-c65b-4cfc-bcd1-2c67d63d65eb'	System	15 Aug 2020 18:01:23
User entered 'None (0)'	System	15 Aug 2020 18:01:23

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-15T13:01:08', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '26481b1a-c65b-4cfc-bcd1-2c67d63d65eb'	System	15 Aug 2020 18:01:23
User entered 'None (0)'	System	15 Aug 2020 18:01:23

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-15T13:01:10', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '26481b1a-c65b-4cfc-bcd1-2c67d63d65eb'	System	15 Aug 2020 18:01:23
User entered 'None (0)'	System	15 Aug 2020 18:01:23

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-15T13:01:11', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '26481b1a-c65b-4cfc-bcd1-2c67d63d65eb'	System	15 Aug 2020 18:01:23
User entered 'None (0)'	System	15 Aug 2020 18:01:23

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-15T13:01:13', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '26481b1a-c65b-4cfc-bcd1-2c67d63d65eb'	System	15 Aug 2020 18:01:23
User entered 'None (0)'	System	15 Aug 2020 18:01:23

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-15T13:01:16', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '26481b1a-c65b-4cfc-bcd1-2c67d63d65eb'	System	15 Aug 2020 18:01:23
User entered 'No (N)'	System	15 Aug 2020 18:01:23

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-15T13:01:18', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '26481b1a-c65b-4cfc-bcd1-2c67d63d65eb'	System	15 Aug 2020 18:01:23
User entered '15 Aug 2020 13:01'	System	15 Aug 2020 18:01:23

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 7'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-16T15:54:44', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a8943e15-ffe7-473a-bb59-ced3564bf672'	System	16 Aug 2020 20:55:09
User entered 'No interference with activity (1)'	System	16 Aug 2020 20:55:09

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-16T15:54:46', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a8943e15-ffe7-473a-bb59-ced3564bf672'	System	16 Aug 2020 20:55:09
User entered 'None (0)'	System	16 Aug 2020 20:55:09

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-16T15:54:49', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a8943e15-ffe7-473a-bb59-ced3564bf672'	System	16 Aug 2020 20:55:09
User entered 'None (0)'	System	16 Aug 2020 20:55:09

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-16T15:54:53', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a8943e15-ffe7-473a-bb59-ced3564bf672'	System	16 Aug 2020 20:55:09
User entered 'None (0)'	System	16 Aug 2020 20:55:09

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-16T15:54:55', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a8943e15-ffe7-473a-bb59-ced3564bf672'	System	16 Aug 2020 20:55:09
User entered 'None (0)'	System	16 Aug 2020 20:55:09

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-16T15:54:59', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a8943e15-ffe7-473a-bb59-ced3564bf672'	System	16 Aug 2020 20:55:09
User entered 'None (0)'	System	16 Aug 2020 20:55:09

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-16T15:55:03', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a8943e15-ffe7-473a-bb59-ced3564bf672'	System	16 Aug 2020 20:55:09
User entered 'No (N)'	System	16 Aug 2020 20:55:09

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-16T15:55:07', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a8943e15-ffe7-473a-bb59-ced3564bf672'	System	16 Aug 2020 20:55:09
User entered '16 Aug 2020 15:55'	System	16 Aug 2020 20:55:09

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	16 Aug 2020 20:56:31
User entered 'Day 8'	System	16 Aug 2020 20:56:31

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-17T14:43:31', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '522fc0a5-797b-499a-9916-a82500229e48'	System	17 Aug 2020 19:43:41
User entered 'Does not interfere with activity (2)'	System	17 Aug 2020 19:43:41

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-17T14:43:37', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '522fc0a5-797b-499a-9916-a82500229e48'	System	17 Aug 2020 19:43:41
User entered '17 Aug 2020 14:43'	System	17 Aug 2020 19:43:41

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 20:56:31

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 20:56:31

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	16 Aug 2020 20:56:31
User entered 'Day 9'	System	16 Aug 2020 20:56:31

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-18T12:55:14', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'd0f8ea43-f0f5-4176-8f97-0351306aa648'	System	18 Aug 2020 17:55:19
User entered 'Does not interfere with activity (2)'	System	18 Aug 2020 17:55:19

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-18T12:55:16', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'd0f8ea43-f0f5-4176-8f97-0351306aa648'	System	18 Aug 2020 17:55:19
User entered '18 Aug 2020 12:55'	System	18 Aug 2020 17:55:19

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 20:56:31

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 20:56:31

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	17 Aug 2020 19:43:41
User entered 'Day 10'	System	17 Aug 2020 19:43:41

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-19T13:52:09', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0bf8eb55-1edf-4b09-92e9-6d45fa5b2440'	System	19 Aug 2020 18:52:14
User entered 'Does not interfere with activity (2)'	System	19 Aug 2020 18:52:14

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-19T13:52:12', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0bf8eb55-1edf-4b09-92e9-6d45fa5b2440'	System	19 Aug 2020 18:52:14
User entered '19 Aug 2020 13:52'	System	19 Aug 2020 18:52:14

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 19:43:41

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 19:43:41

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(11)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	18 Aug 2020 17:55:19
User entered 'Day 11'	System	18 Aug 2020 17:55:19

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(11)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-20T12:11:37', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '6883522d-5c58-4e65-994d-51d0f51a84d7'	System	20 Aug 2020 17:11:44
User entered 'None (1)'	System	20 Aug 2020 17:11:44

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(11)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-20T12:11:41', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '6883522d-5c58-4e65-994d-51d0f51a84d7'	System	20 Aug 2020 17:11:44
User entered '20 Aug 2020 12:11'	System	20 Aug 2020 17:11:44

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(11)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 17:55:19

US3212100

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(11)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 17:55:19

US3212100

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	16 Aug 2020 20:55:09
User entered 'Day 8'	System	16 Aug 2020 20:55:09

US3212100

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:47:13

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-17T14:43:49', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '840ed0fb-9096-4dd7-a074-16589133d5fc'	System	17 Aug 2020 19:43:54
User entered 'None (0)'	System	17 Aug 2020 19:43:54

US3212100

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-17T14:43:53', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '840ed0fb-9096-4dd7-a074-16589133d5fc'	System	17 Aug 2020 19:43:54
User entered '17 Aug 2020 14:43'	System	17 Aug 2020 19:43:54

US3212100

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 20:55:09

US3212100

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 20:55:09

US3212100

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	16 Aug 2020 20:55:09
User entered 'Day 8'	System	16 Aug 2020 20:55:09

US3212100

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-17T14:43:44', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b0021627-2a10-4899-8b33-25b37a567f20'	System	17 Aug 2020 19:43:47
User entered 'No (N)'	System	17 Aug 2020 19:43:47

US3212100

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:47:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-17T14:43:46', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b0021627-2a10-4899-8b33-25b37a567f20'	System	17 Aug 2020 19:43:47
User entered '17 Aug 2020 14:43'	System	17 Aug 2020 19:43:47

US3212100

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 20:55:09

US3212100

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 20:55:09

US3212100

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	16 Aug 2020 20:55:09
User entered 'Day 9'	System	16 Aug 2020 20:55:09

US3212100

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-18T12:55:21', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '1bd997fa-54b6-44c8-a0b8-85b05e4fa650'	System	18 Aug 2020 17:55:30
User entered 'No (N)'	System	18 Aug 2020 17:55:30

US3212100

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:47:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-18T12:55:24', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '1bd997fa-54b6-44c8-a0b8-85b05e4fa650'	System	18 Aug 2020 17:55:30
User entered '18 Aug 2020 12:55'	System	18 Aug 2020 17:55:30

US3212100

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 20:55:09

US3212100

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 20:55:09

US3212100

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	17 Aug 2020 19:43:41
User entered 'Day 10'	System	17 Aug 2020 19:43:41

US3212100

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-19T13:52:18', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '4b7fd5df-51d4-474a-ba92-3bd9e9a5d56f'	System	19 Aug 2020 18:52:24
User entered 'No (N)'	System	19 Aug 2020 18:52:24

US3212100

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:47:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-19T13:52:20', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '4b7fd5df-51d4-474a-ba92-3bd9e9a5d56f'	System	19 Aug 2020 18:52:24
User entered '19 Aug 2020 13:52'	System	19 Aug 2020 18:52:24

US3212100

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 19:43:41

US3212100

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 19:43:41

US3212100

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	18 Aug 2020 17:55:19
User entered 'Day 11'	System	18 Aug 2020 17:55:19

US3212100

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-20T12:11:45', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '620fa36b-4dba-4653-a306-e7309673387a'	System	20 Aug 2020 17:11:51
User entered 'No (N)'	System	20 Aug 2020 17:11:51

US3212100

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:47:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-08-20T12:11:48', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '620fa36b-4dba-4653-a306-e7309673387a'	System	20 Aug 2020 17:11:51
User entered '20 Aug 2020 12:11'	System	20 Aug 2020 17:11:51

US3212100

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 17:55:19

US3212100

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 17:55:19

US3212100

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Heather Leary (b) (4) (b) (4)	18 Aug 2020 21:07:13

US3212100

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '17 Aug 2020'	(b) (4) Heather Leary (b) (4) (b) (4)	18 Aug 2020 21:07:13

US3212100

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Heather Leary (b) (4) (b) (4)	18 Aug 2020 21:07:13

US3212100

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Heather Leary (b) (4) (b) (4)	18 Aug 2020 21:07:13

US3212100

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Heather Leary (b) (4) (b) (4)	18 Aug 2020 21:07:01

US3212100

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'I'	System	18 Aug 2020 21:07:01

US3212100

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:19:01

US3212100

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '24 Aug 2020'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:19:01

US3212100

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:19:01

US3212100

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:19:01

US3212100

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:19:09

US3212100

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'I'	System	25 Aug 2020 16:19:09

US3212100

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	01 Sep 2020 13:59:13

US3212100

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '31 Aug 2020'	(b) (4) Laura Ngansop Djampou (b) (4)	01 Sep 2020 13:59:13

US3212100

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Laura Ngansop Djampou (b) (4)	01 Sep 2020 13:59:13

US3212100

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	01 Sep 2020 13:59:13

US3212100

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	01 Sep 2020 13:59:19

US3212100

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'I'	System	01 Sep 2020 13:59:19

US3212100

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	08 Sep 2020 19:10:00

US3212100

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered '08 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Dec 2020 15:47:47
User entered '8 Sep 2020'	Afifah Ayub (b) (4)	08 Sep 2020 19:10:00
	(b) (4)	

US3212100

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

[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 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Clinic (Clinic)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	08 Sep 2020 19:10:00

US3212100

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'VISIT2'	System	08 Sep 2020 19:10:00

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User accepted default value 'Pre-Dose (PREDOSE)'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 20:41:45

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Sep 2020 20:41:45

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered '08 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Dec 2020 15:48:00
User entered '8 Sep 2020'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 20:41:45

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '13:12'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Sep 2020 20:41:45

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered '08 Sep 2020 13:12'	System	08 Dec 2020 15:48:00
User entered '8 Sep 2020 13:12'	System	08 Sep 2020 20:41:45

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '98.2' F	(b) (4) Laura Ngansop Djampou (b) (4)	08 Sep 2020 20:41:45

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Oral (Oral)'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Sep 2020 20:41:45

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	08 Sep 2020 20:41:45

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '76'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Sep 2020 20:41:45

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'bpm'	System	08 Sep 2020 20:41:45

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '15'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Sep 2020 20:41:45

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'breaths/min'	System	08 Sep 2020 20:41:45

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '117'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Sep 2020 20:41:45

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'mmHg'	System	08 Sep 2020 20:41:45

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '79'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Sep 2020 20:41:45

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:47:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'mmHg'	System	08 Sep 2020 20:41:45

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User accepted default value 'Post-Dose (POSTDOSE)'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 20:42:47

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Sep 2020 20:42:47

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered '08 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Dec 2020 15:48:00
User entered '8 Sep 2020'	Laura Ngansop Djampou (b) (4)	08 Sep 2020 20:42:47

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '15:17'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Sep 2020 20:42:47

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered '08 Sep 2020 15:17'	System	08 Dec 2020 15:48:00
User entered '8 Sep 2020 15:17'	System	08 Sep 2020 20:42:47

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '98.5' F	(b) (4) Laura Ngansop Djampou (b) (4)	08 Sep 2020 20:42:47

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Oral (Oral)'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Sep 2020 20:42:47

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	08 Sep 2020 20:42:47

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '72'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Sep 2020 20:42:47

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'bpm'	System	08 Sep 2020 20:42:47

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '16'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Sep 2020 20:42:47

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'breaths/min'	System	08 Sep 2020 20:42:47

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '125'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Sep 2020 20:42:47

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'mmHg'	System	08 Sep 2020 20:42:47

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '80'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Sep 2020 20:42:47

US3212100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:47:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'mmHg'	System	08 Sep 2020 20:42:47

US3212100

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:47:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	08 Sep 2020 19:10:23

US3212100

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:47:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered '08 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Dec 2020 15:47:52
User entered '8 Sep 2020'	Afifah Ayub (b) (4)	08 Sep 2020 19:10:23
	(b) (4)	

US3212100

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:47:13

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	08 Sep 2020 19:10:40

US3212100

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:47:13

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '8 Sep 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	08 Sep 2020 19:10:40

US3212100

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:47:13

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Urine (URINE)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	08 Sep 2020 19:10:40

US3212100

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:47:13

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Negative (NEGATIVE)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	08 Sep 2020 19:10:40

US3212100

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:47:13

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	08 Sep 2020 19:10:40

US3212100

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:47:13

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	08 Sep 2020 19:10:40

US3212100

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:47:13

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	08 Sep 2020 19:10:40

US3212100

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered empty.	System	08 Sep 2020 19:10:40

US3212100

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:47:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	08 Sep 2020 19:11:21

US3212100

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:47:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	08 Sep 2020 19:11:21

US3212100

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:47:13

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 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	08 Sep 2020 19:11:21

US3212100

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:47:13

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 19:11:21

US3212100

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered '08 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Dec 2020 15:48:12
User entered '8 Sep 2020'	Afifah Ayub (b) (4)	08 Sep 2020 19:11:21
	(b) (4)	

US3212100

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '14:07'	(b) (4) Afifah Ayub (b) (4) (b) (4)	08 Sep 2020 19:11:21

US3212100

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered '08 Sep 2020 14:07'	System	08 Dec 2020 15:48:12
User entered '8 Sep 2020 14:07'	System	08 Sep 2020 19:11:21

US3212100

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Left Arm (LEFT ARM)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	08 Sep 2020 19:11:21

US3212100

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'ONCE'	System	08 Sep 2020 19:11:21

US3212100

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 19:11:21

US3212100

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:47:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	08 Sep 2020 21:17:25

US3212100

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:47:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered '08 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Dec 2020 15:48:17
User entered '8 Sep 2020'	Afifah Ayub (b) (4)	08 Sep 2020 21:17:25
	(b) (4)	

US3212100

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '14:02'	(b) (4) Afifah Ayub (b) (4) (b) (4)	08 Sep 2020 21:17:25

US3212100

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered '08 Sep 2020 14:02'	System	08 Dec 2020 15:48:17
User entered '8 Sep 2020 14:02'	System	08 Sep 2020 21:17:25

US3212100

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:47:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered '08 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Dec 2020 15:48:25
User entered '8 Sep 2020'	Afifah Ayub (b) (4)	08 Sep 2020 21:17:37
	(b) (4)	

US3212100

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:47:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Afifah Ayub (b) (4) (b) (4)	08 Sep 2020 21:17:37

US3212100

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:47:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	08 Sep 2020 21:17:37

US3212100

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '13:58'	(b) (4) Afifah Ayub (b) (4) (b) (4)	08 Sep 2020 21:17:37

US3212100

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered '08 Sep 2020 13:58'	System	08 Dec 2020 15:48:25
User entered '8 Sep 2020 13:58'	System	08 Sep 2020 21:17:37

US3212100

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:47:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Afifah Ayub (b) (4) (b) (4)	08 Sep 2020 21:17:37

US3212100

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:47:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	08 Sep 2020 21:17:37

US3212100

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:47:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	08 Sep 2020 21:17:37

US3212100

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered empty.	System	08 Sep 2020 21:17:37

US3212100

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	08 Sep 2020 21:17:43

US3212100

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'I'	System	08 Sep 2020 21:17:43

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	08 Sep 2020 19:11:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T15:16:46', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '355aa2f1-798d-47a3-9077-23fc2704aec0'	System	08 Sep 2020 20:17:03
User entered 'Yes (Y)'	System	08 Sep 2020 20:17:03

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T15:16:53', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '355aa2f1-798d-47a3-9077-23fc2704aec0'	System	08 Sep 2020 20:17:03
User entered '98.5'	System	08 Sep 2020 20:17:03

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T15:16:56', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '355aa2f1-798d-47a3-9077-23fc2704aec0'	System	08 Sep 2020 20:17:03
User entered 'No (N)'	System	08 Sep 2020 20:17:03

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T15:16:58', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '355aa2f1-798d-47a3-9077-23fc2704aec0'	System	08 Sep 2020 20:17:03
User entered '08 Sep 2020 15:16'	System	08 Sep 2020 20:17:03

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '08 Sep 2020 14:27'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '08 Sep 2020 16:57'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	08 Sep 2020 19:11:21
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T17:56:46', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'd4629204-484c-4a51-bbab-8c032b22332f'	System	08 Sep 2020 22:57:37
User entered 'Yes (Y)'	System	08 Sep 2020 22:57:37

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T17:57:26', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'd4629204-484c-4a51-bbab-8c032b22332f' User entered '98.9'	System	08 Sep 2020 22:57:37

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T17:57:29', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'd4629204-484c-4a51-bbab-8c032b22332f'	System	08 Sep 2020 22:57:37
User entered 'No (N)'	System	08 Sep 2020 22:57:37

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T17:57:32', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'd4629204-484c-4a51-bbab-8c032b22332f' User entered '08 Sep 2020 17:57'	System	08 Sep 2020 22:57:37
	System	08 Sep 2020 22:57:37

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '08 Sep 2020 17:52'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	08 Sep 2020 19:11:21
User entered 'Day 2'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:47:13

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-09T12:03:25', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '9ccf3418-a76e-4ad0-8adb-cc14def5e9b1'	System	09 Sep 2020 17:04:55
User entered 'Yes (Y)'	System	09 Sep 2020 17:04:55

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:47:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-09T12:03:30', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '9ccf3418-a76e-4ad0-8adb-cc14def5e9b1'	System	09 Sep 2020 17:04:55
User entered '98.9'	System	09 Sep 2020 17:04:55

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-09T12:03:32', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '9ccf3418-a76e-4ad0-8adb-cc14def5e9b1'	System	09 Sep 2020 17:04:55
User entered 'Yes (Y)'	System	09 Sep 2020 17:04:55

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
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 'updated' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 16:18:34
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 (7a4408d64bb91427)', Time: '2020-09-09T12:03:41', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '9ccf3418-a76e-4ad0-8adb-cc14def5e9b1'	Afifah Ayub (b) (4) (b) (4)	18 Sep 2020 17:35:30
User entered '1'	System	09 Sep 2020 17:04:55

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:47:13

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-09T12:03:41', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '9ccf3418-a76e-4ad0-8adb-cc14def5e9b1'	System	09 Sep 2020 17:04:55
User entered '0'	System	09 Sep 2020 17:04:55

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-09T12:03:44', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '9ccf3418-a76e-4ad0-8adb-cc14def5e9b1'	System	09 Sep 2020 17:04:55
User entered '09 Sep 2020 12:03'	System	09 Sep 2020 17:04:55

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	08 Sep 2020 19:11:21
User entered 'Day 3'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:47:13

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-10T12:45:04', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'e519dac0-1476-4ae7-b0af-d086a24cc670'	System	10 Sep 2020 17:45:20
User entered 'Yes (Y)'	System	10 Sep 2020 17:45:20

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:47:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-10T12:45:07', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'e519dac0-1476-4ae7-b0af-d086a24cc670'	System	10 Sep 2020 17:45:20
User entered '98.9'	System	10 Sep 2020 17:45:20

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-10T12:45:13', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'e519dac0-1476-4ae7-b0af-d086a24cc670'	System	10 Sep 2020 17:45:20
User entered 'No (N)'	System	10 Sep 2020 17:45:20

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-10T12:45:16', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'e519dac0-1476-4ae7-b0af-d086a24cc670'	System	10 Sep 2020 17:45:20
User entered '10 Sep 2020 12:45'	System	10 Sep 2020 17:45:20

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	08 Sep 2020 19:11:21
User entered 'Day 4'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:47:13

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-11T13:27:23', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'cbfc07a1-9b62-46c5-8931-6f056c4421b0'	System	11 Sep 2020 18:27:50
User entered 'Yes (Y)'	System	11 Sep 2020 18:27:50

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:47:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-11T13:27:26', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'cbfc07a1-9b62-46c5-8931-6f056c4421b0'	System	11 Sep 2020 18:27:50
User entered '98.4'	System	11 Sep 2020 18:27:50

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-11T13:27:29', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'cbfc07a1-9b62-46c5-8931-6f056c4421b0'	System	11 Sep 2020 18:27:50
User entered 'Yes (Y)'	System	11 Sep 2020 18:27:50

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
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 'updated' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 16:18:47
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).	System	11 Sep 2020 18:27:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-11T13:27:36', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'cbfc07a1-9b62-46c5-8931-6f056c4421b0'	System	11 Sep 2020 18:27:50
User entered '1'	System	11 Sep 2020 18:27:50

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:47:13

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-11T13:27:36', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'cbfc07a1-9b62-46c5-8931-6f056c4421b0'	System	11 Sep 2020 18:27:50
User entered '0'	System	11 Sep 2020 18:27:50

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-11T13:27:39', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'cbfc07a1-9b62-46c5-8931-6f056c4421b0'	System	11 Sep 2020 18:27:50
User entered '11 Sep 2020 13:27'	System	11 Sep 2020 18:27:50

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	08 Sep 2020 19:11:21
User entered 'Day 5'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:47:13

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-12T12:12:26', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'd0d148bd-9316-4dc6-9fc1-e447fbfce91a'	System	12 Sep 2020 17:12:36
User entered 'Yes (Y)'	System	12 Sep 2020 17:12:36

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:47:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-12T12:12:29', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'd0d148bd-9316-4dc6-9fc1-e447fbfce91a'	System	12 Sep 2020 17:12:36
User entered '98.1'	System	12 Sep 2020 17:12:36

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-12T12:12:32', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'd0d148bd-9316-4dc6-9fc1-e447fbfce91a'	System	12 Sep 2020 17:12:36
User entered 'No (N)'	System	12 Sep 2020 17:12:36

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-12T12:12:34', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'd0d148bd-9316-4dc6-9fc1-e447fbfce91a'	System	12 Sep 2020 17:12:36
User entered '12 Sep 2020 12:12'	System	12 Sep 2020 17:12:36

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	08 Sep 2020 19:11:21
User entered 'Day 6'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:47:13

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-13T16:16:05', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '9ebca2db-7146-462c-b360-5f6eef715374'	System	13 Sep 2020 21:16:22
User entered 'Yes (Y)'	System	13 Sep 2020 21:16:22

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:47:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-13T16:16:11', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '9ebca2db-7146-462c-b360-5f6eef715374'	System	13 Sep 2020 21:16:22
User entered '98.1'	System	13 Sep 2020 21:16:22

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-13T16:16:14', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '9ebca2db-7146-462c-b360-5f6eef715374'	System	13 Sep 2020 21:16:22
User entered 'No (N)'	System	13 Sep 2020 21:16:22

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-13T16:16:17', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '9ebca2db-7146-462c-b360-5f6eef715374'	System	13 Sep 2020 21:16:22
User entered '13 Sep 2020 16:16'	System	13 Sep 2020 21:16:22

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	08 Sep 2020 19:11:21
User entered 'Day 7'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:47:13

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-14T15:01:57', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '95b630cf-59cc-445b-a4c7-7d4f7b92e765'	System	14 Sep 2020 20:02:16
User entered 'Yes (Y)'	System	14 Sep 2020 20:02:16

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:47:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-14T15:02:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '95b630cf-59cc-445b-a4c7-7d4f7b92e765'	System	14 Sep 2020 20:02:16
User entered '98.7'	System	14 Sep 2020 20:02:16

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-14T15:02:04', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '95b630cf-59cc-445b-a4c7-7d4f7b92e765'	System	14 Sep 2020 20:02:16
User entered 'Yes (Y)'	System	14 Sep 2020 20:02:16

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-14T15:02:11', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '95b630cf-59cc-445b-a4c7-7d4f7b92e765'	System	14 Sep 2020 20:02:16
User entered '0'	System	14 Sep 2020 20:02:16

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:47:13

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'updated' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 16:19:11
User opened query 'Per the participant response, medication was taken to prevent 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 (7a4408d64bb91427)', Time: '2020-09-14T15:02:11', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '95b630cf-59cc-445b-a4c7-7d4f7b92e765'	Afifah Ayub (b) (4) (b) (4)	18 Sep 2020 17:35:58
User entered '1'	System	14 Sep 2020 20:02:16
	System	14 Sep 2020 20:02:16
	System	14 Sep 2020 20:02:16

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-14T15:02:13', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '95b630cf-59cc-445b-a4c7-7d4f7b92e765'	System	14 Sep 2020 20:02:16
User entered '14 Sep 2020 15:02'	System	14 Sep 2020 20:02:16

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	14 Sep 2020 20:02:16
User entered 'Day 8'	System	14 Sep 2020 20:02:16

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:47:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-15T12:37:07', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a4b6ffb4-5bd5-4340-a767-22c66ba8e0b4'	System	15 Sep 2020 17:37:31
User entered 'Yes (Y)'	System	15 Sep 2020 17:37:31

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:47:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-15T12:37:13', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a4b6ffb4-5bd5-4340-a767-22c66ba8e0b4'	System	15 Sep 2020 17:37:31
User entered '98.7'	System	15 Sep 2020 17:37:31

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-15T12:37:26', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a4b6ffb4-5bd5-4340-a767-22c66ba8e0b4'	System	15 Sep 2020 17:37:31
User entered 'No (N)'	System	15 Sep 2020 17:37:31

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-15T12:37:28', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a4b6ffb4-5bd5-4340-a767-22c66ba8e0b4'	System	15 Sep 2020 17:37:31
User entered '15 Sep 2020 12:37'	System	15 Sep 2020 17:37:31

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 20:02:16

US3212100

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 20:02:16

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	08 Sep 2020 19:11:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T15:17:02', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b0940c2d-2c48-44bf-b7e4-1835e14ea1ea'	System	08 Sep 2020 20:17:37
User entered 'None (1)'	System	08 Sep 2020 20:17:37

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T15:17:12', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b0940c2d-2c48-44bf-b7e4-1835e14ea1ea'	System	08 Sep 2020 20:17:37
User entered 'No (N)'	System	08 Sep 2020 20:17:37

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T15:17:20', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b0940c2d-2c48-44bf-b7e4-1835e14ea1ea'	System	08 Sep 2020 20:17:37
User entered 'No (N)'	System	08 Sep 2020 20:17:37

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T15:17:29', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b0940c2d-2c48-44bf-b7e4-1835e14ea1ea'	System	08 Sep 2020 20:17:37
User entered 'None (1)'	System	08 Sep 2020 20:17:37

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T15:17:31', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b0940c2d-2c48-44bf-b7e4-1835e14ea1ea'	System	08 Sep 2020 20:17:37
User entered '08 Sep 2020 15:17'	System	08 Sep 2020 20:17:37

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '08 Sep 2020 14:27'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '08 Sep 2020 16:57'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	08 Sep 2020 19:11:21
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T17:55:18', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a3a8f949-4c20-4e3e-8a7d-ae83f5fd1759'	System	08 Sep 2020 22:56:04
User entered 'Does not interfere with activity (2)'	System	08 Sep 2020 22:56:04

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T17:55:22', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a3a8f949-4c20-4e3e-8a7d-ae83f5fd1759'	System	08 Sep 2020 22:56:04
User entered 'No (N)'	System	08 Sep 2020 22:56:04

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T17:55:45', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a3a8f949-4c20-4e3e-8a7d-ae83f5fd1759'	System	08 Sep 2020 22:56:04
User entered 'No (N)'	System	08 Sep 2020 22:56:04

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T17:55:54', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a3a8f949-4c20-4e3e-8a7d-ae83f5fd1759'	System	08 Sep 2020 22:56:04
User entered 'None (1)'	System	08 Sep 2020 22:56:04

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T17:55:57', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a3a8f949-4c20-4e3e-8a7d-ae83f5fd1759'	System	08 Sep 2020 22:56:04
User entered '08 Sep 2020 17:55'	System	08 Sep 2020 22:56:04

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '08 Sep 2020 17:52'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	08 Sep 2020 19:11:21
User entered 'Day 2'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-09T12:05:45', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '54567737-7269-40fb-b2f7-f934d4cb412b'	System	09 Sep 2020 17:06:06
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		09 Sep 2020 17:06:06

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-09T12:05:48', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '54567737-7269-40fb-b2f7-f934d4cb412b'	System	09 Sep 2020 17:06:06
User entered 'No (N)'	System	09 Sep 2020 17:06:06

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-09T12:05:51', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '54567737-7269-40fb-b2f7-f934d4cb412b'	System	09 Sep 2020 17:06:06
User entered 'No (N)'	System	09 Sep 2020 17:06:06

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-09T12:05:59', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '54567737-7269-40fb-b2f7-f934d4cb412b'	System	09 Sep 2020 17:06:06
User entered 'None (1)'	System	09 Sep 2020 17:06:06

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-09T12:06:02', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '54567737-7269-40fb-b2f7-f934d4cb412b'	System	09 Sep 2020 17:06:06
User entered '09 Sep 2020 12:06'	System	09 Sep 2020 17:06:06

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	08 Sep 2020 19:11:21
User entered 'Day 3'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-10T12:45:55', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '4c01e1c1-a52e-48b8-8634-55b300b3ac05'	System	10 Sep 2020 17:46:14
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 17:46:14

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-10T12:45:57', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '4c01e1c1-a52e-48b8-8634-55b300b3ac05'	System	10 Sep 2020 17:46:14
User entered 'No (N)'	System	10 Sep 2020 17:46:14

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-10T12:46:03', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '4c01e1c1-a52e-48b8-8634-55b300b3ac05'	System	10 Sep 2020 17:46:14
User entered 'No (N)'	System	10 Sep 2020 17:46:14

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-10T12:46:08', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '4c01e1c1-a52e-48b8-8634-55b300b3ac05'	System	10 Sep 2020 17:46:14
User entered 'None (1)'	System	10 Sep 2020 17:46:14

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-10T12:46:10', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '4c01e1c1-a52e-48b8-8634-55b300b3ac05'	System	10 Sep 2020 17:46:14
User entered '10 Sep 2020 12:46'	System	10 Sep 2020 17:46:14

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	08 Sep 2020 19:11:21
User entered 'Day 4'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-11T13:27:49', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '5450927e-5c30-454e-a535-693eed291ac6'	System	11 Sep 2020 18:28:07
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 18:28:07

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-11T13:27:51', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '5450927e-5c30-454e-a535-693eed291ac6'	System	11 Sep 2020 18:28:07
User entered 'No (N)'	System	11 Sep 2020 18:28:07

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-11T13:27:54', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '5450927e-5c30-454e-a535-693eed291ac6'	System	11 Sep 2020 18:28:07
User entered 'No (N)'	System	11 Sep 2020 18:28:07

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-11T13:28:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '5450927e-5c30-454e-a535-693eed291ac6'	System	11 Sep 2020 18:28:07
User entered 'None (1)'	System	11 Sep 2020 18:28:07

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-11T13:28:02', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '5450927e-5c30-454e-a535-693eed291ac6'	System	11 Sep 2020 18:28:07
User entered '11 Sep 2020 13:28'	System	11 Sep 2020 18:28:07

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	08 Sep 2020 19:11:21
User entered 'Day 5'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-12T12:12:46', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'eb5a9f13-db8e-490c-81f4-556adcd04fc0'	System	12 Sep 2020 17:13:07
User entered 'None (1)'	System	12 Sep 2020 17:13:07

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-12T12:12:49', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'eb5a9f13-db8e-490c-81f4-556adcd04fc0'	System	12 Sep 2020 17:13:07
User entered 'No (N)'	System	12 Sep 2020 17:13:07

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-12T12:12:57', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'eb5a9f13-db8e-490c-81f4-556adcd04fc0'	System	12 Sep 2020 17:13:07
User entered 'No (N)'	System	12 Sep 2020 17:13:07

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-12T12:13:03', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'eb5a9f13-db8e-490c-81f4-556adcd04fc0'	System	12 Sep 2020 17:13:07
User entered 'None (1)'	System	12 Sep 2020 17:13:07

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-12T12:13:05', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'eb5a9f13-db8e-490c-81f4-556adcd04fc0'	System	12 Sep 2020 17:13:07
User entered '12 Sep 2020 12:13'	System	12 Sep 2020 17:13:07

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	08 Sep 2020 19:11:21
User entered 'Day 6'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-13T16:16:44', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'af335fa6-81e4-4d34-bc49-e31d32f004f8'	System	13 Sep 2020 21:17:01
User entered 'None (1)'	System	13 Sep 2020 21:17:01

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:47:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-13T16:16:48', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'af335fa6-81e4-4d34-bc49-e31d32f004f8'	System	13 Sep 2020 21:17:01
User entered 'No (N)'	System	13 Sep 2020 21:17:01

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-13T16:16:51', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'af335fa6-81e4-4d34-bc49-e31d32f004f8'	System	13 Sep 2020 21:17:01
User entered 'No (N)'	System	13 Sep 2020 21:17:01

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-13T16:16:57', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'af335fa6-81e4-4d34-bc49-e31d32f004f8'	System	13 Sep 2020 21:17:01
User entered 'None (1)'	System	13 Sep 2020 21:17:01

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-13T16:16:59', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'af335fa6-81e4-4d34-bc49-e31d32f004f8'	System	13 Sep 2020 21:17:01
User entered '13 Sep 2020 16:16'	System	13 Sep 2020 21:17:01

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	08 Sep 2020 19:11:21
User entered 'Day 7'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-14T15:02:19', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '242128ca-7e32-4610-a420-520c175a4ee4'	System	14 Sep 2020 20:02:33
User entered 'None (1)'	System	14 Sep 2020 20:02:33

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-14T15:02:23', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '242128ca-7e32-4610-a420-520c175a4ee4'	System	14 Sep 2020 20:02:33
User entered 'No (N)'	System	14 Sep 2020 20:02:33

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-14T15:02:27', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '242128ca-7e32-4610-a420-520c175a4ee4'	System	14 Sep 2020 20:02:33
User entered 'No (N)'	System	14 Sep 2020 20:02:33

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-14T15:02:28', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '242128ca-7e32-4610-a420-520c175a4ee4'	System	14 Sep 2020 20:02:33
User entered 'None (1)'	System	14 Sep 2020 20:02:33

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:47:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-14T15:02:30', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '242128ca-7e32-4610-a420-520c175a4ee4'	System	14 Sep 2020 20:02:33
User entered '14 Sep 2020 15:02'	System	14 Sep 2020 20:02:33

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	08 Sep 2020 19:11:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T15:17:35', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '37d72523-c6c0-42af-826d-d910343b4023'	System	08 Sep 2020 20:17:58
User entered 'None (0)'	System	08 Sep 2020 20:17:58

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T15:17:37', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '37d72523-c6c0-42af-826d-d910343b4023'	System	08 Sep 2020 20:17:58
User entered 'None (0)'	System	08 Sep 2020 20:17:58

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T15:17:39', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '37d72523-c6c0-42af-826d-d910343b4023'	System	08 Sep 2020 20:17:58
User entered 'None (0)'	System	08 Sep 2020 20:17:58

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T15:17:42', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '37d72523-c6c0-42af-826d-d910343b4023'	System	08 Sep 2020 20:17:58
User entered 'None (0)'	System	08 Sep 2020 20:17:58

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T15:17:44', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '37d72523-c6c0-42af-826d-d910343b4023'	System	08 Sep 2020 20:17:58
User entered 'None (0)'	System	08 Sep 2020 20:17:58

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T15:17:46', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '37d72523-c6c0-42af-826d-d910343b4023'	System	08 Sep 2020 20:17:58
User entered 'None (0)'	System	08 Sep 2020 20:17:58

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T15:17:52', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '37d72523-c6c0-42af-826d-d910343b4023'	System	08 Sep 2020 20:17:58
User entered 'No (N)'	System	08 Sep 2020 20:17:58

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T15:17:55', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '37d72523-c6c0-42af-826d-d910343b4023'	System	08 Sep 2020 20:17:58
User entered '08 Sep 2020 15:17'	System	08 Sep 2020 20:17:58

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '08 Sep 2020 14:27'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '08 Sep 2020 16:57'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	08 Sep 2020 19:11:21
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T17:56:01', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '8060ced4-6211-4ae5-ab6c-e41dda1e702e'	System	08 Sep 2020 22:56:27
User entered 'None (0)'	System	08 Sep 2020 22:56:27

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T17:56:05', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '8060ced4-6211-4ae5-ab6c-e41dda1e702e'	System	08 Sep 2020 22:56:27
User entered 'Some interference with activity (2)'	System	08 Sep 2020 22:56:27

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T17:56:10', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '8060ced4-6211-4ae5-ab6c-e41dda1e702e'	System	08 Sep 2020 22:56:27
User entered 'No interference with activity (1)'	System	08 Sep 2020 22:56:27

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T17:56:12', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '8060ced4-6211-4ae5-ab6c-e41dda1e702e'	System	08 Sep 2020 22:56:27
User entered 'None (0)'	System	08 Sep 2020 22:56:27

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T17:56:14', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '8060ced4-6211-4ae5-ab6c-e41dda1e702e'	System	08 Sep 2020 22:56:27
User entered 'None (0)'	System	08 Sep 2020 22:56:27

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T17:56:16', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '8060ced4-6211-4ae5-ab6c-e41dda1e702e'	System	08 Sep 2020 22:56:27
User entered 'None (0)'	System	08 Sep 2020 22:56:27

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T17:56:19', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '8060ced4-6211-4ae5-ab6c-e41dda1e702e'	System	08 Sep 2020 22:56:27
User entered 'No (N)'	System	08 Sep 2020 22:56:27

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-08T17:56:25', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '8060ced4-6211-4ae5-ab6c-e41dda1e702e'	System	08 Sep 2020 22:56:27
User entered '08 Sep 2020 17:56'	System	08 Sep 2020 22:56:27

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '08 Sep 2020 17:52'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	08 Sep 2020 19:11:21
User entered 'Day 2'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-09T12:04:54', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '3a428e9e-5678-41f0-8cff-965116743cc8'	System	09 Sep 2020 17:05:54
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		09 Sep 2020 17:05:54

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-09T12:04:42', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '3a428e9e-5678-41f0-8cff-965116743cc8'	System	09 Sep 2020 17:05:54
User entered 'Some interference with activity (2)'	System	09 Sep 2020 17:05:54

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-09T12:04:41', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '3a428e9e-5678-41f0-8cff-965116743cc8'	System	09 Sep 2020 17:05:54
User entered 'Some interference with activity (2)'	System	09 Sep 2020 17:05:54

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-09T12:05:03', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '3a428e9e-5678-41f0-8cff-965116743cc8'	System	09 Sep 2020 17:05:54
User entered 'None (0)'	System	09 Sep 2020 17:05:54

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-09T12:05:02', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '3a428e9e-5678-41f0-8cff-965116743cc8'	System	09 Sep 2020 17:05:54
User entered 'None (0)'	System	09 Sep 2020 17:05:54

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-09T12:05:22', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '3a428e9e-5678-41f0-8cff-965116743cc8'	System	09 Sep 2020 17:05:54
User entered 'Some interference with activity not requiring medical attention (2)'	System	09 Sep 2020 17:05:54

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-09T12:05:17', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '3a428e9e-5678-41f0-8cff-965116743cc8'	System	09 Sep 2020 17:05:54
User entered 'No (N)'	System	09 Sep 2020 17:05:54

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-09T12:05:39', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '3a428e9e-5678-41f0-8cff-965116743cc8'	System	09 Sep 2020 17:05:54
User entered '09 Sep 2020 12:05'	System	09 Sep 2020 17:05:54

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	08 Sep 2020 19:11:21
User entered 'Day 3'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-10T12:45:28', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '1c51be07-ca4a-4a87-bf29-7fa1c68cc340'	System	10 Sep 2020 17:45:51
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		10 Sep 2020 17:45:51

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-10T12:45:33', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '1c51be07-ca4a-4a87-bf29-7fa1c68cc340'	System	10 Sep 2020 17:45:51
User entered 'Some interference with activity (2)'	System	10 Sep 2020 17:45:51

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-10T12:45:36', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '1c51be07-ca4a-4a87-bf29-7fa1c68cc340'	System	10 Sep 2020 17:45:51
User entered 'Some interference with activity (2)'	System	10 Sep 2020 17:45:51

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-10T12:45:39', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '1c51be07-ca4a-4a87-bf29-7fa1c68cc340'	System	10 Sep 2020 17:45:51
User entered 'None (0)'	System	10 Sep 2020 17:45:51

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-10T12:45:42', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '1c51be07-ca4a-4a87-bf29-7fa1c68cc340'	System	10 Sep 2020 17:45:51
User entered 'None (0)'	System	10 Sep 2020 17:45:51

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-10T12:45:44', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '1c51be07-ca4a-4a87-bf29-7fa1c68cc340'	System	10 Sep 2020 17:45:51
User entered 'Some interference with activity not requiring medical attention (2)'	System	10 Sep 2020 17:45:51

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-10T12:45:48', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '1c51be07-ca4a-4a87-bf29-7fa1c68cc340'	System	10 Sep 2020 17:45:51
User entered 'No (N)'	System	10 Sep 2020 17:45:51

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-10T12:45:49', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '1c51be07-ca4a-4a87-bf29-7fa1c68cc340'	System	10 Sep 2020 17:45:51
User entered '10 Sep 2020 12:45'	System	10 Sep 2020 17:45:51

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	08 Sep 2020 19:11:21
User entered 'Day 4'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-11T13:28:08', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b4767c60-ae3e-4ebf-b1e8-1441e6f45c5f'	System	11 Sep 2020 18:28:34
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		11 Sep 2020 18:28:34

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-11T13:28:13', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b4767c60-ae3e-4ebf-b1e8-1441e6f45c5f'	System	11 Sep 2020 18:28:34
User entered 'Some interference with activity (2)'	System	11 Sep 2020 18:28:34

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-11T13:28:16', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b4767c60-ae3e-4ebf-b1e8-1441e6f45c5f'	System	11 Sep 2020 18:28:34
User entered 'Some interference with activity (2)'	System	11 Sep 2020 18:28:34

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-11T13:28:18', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b4767c60-ae3e-4ebf-b1e8-1441e6f45c5f'	System	11 Sep 2020 18:28:34
User entered 'None (0)'	System	11 Sep 2020 18:28:34

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-11T13:28:20', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b4767c60-ae3e-4ebf-b1e8-1441e6f45c5f'	System	11 Sep 2020 18:28:34
User entered 'None (0)'	System	11 Sep 2020 18:28:34

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-11T13:28:26', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b4767c60-ae3e-4ebf-b1e8-1441e6f45c5f'	System	11 Sep 2020 18:28:34
User entered 'Some interference with activity not requiring medical attention (2)'	System	11 Sep 2020 18:28:34

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-11T13:28:30', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b4767c60-ae3e-4ebf-b1e8-1441e6f45c5f'	System	11 Sep 2020 18:28:34
User entered 'No (N)'	System	11 Sep 2020 18:28:34

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-11T13:28:32', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b4767c60-ae3e-4ebf-b1e8-1441e6f45c5f'	System	11 Sep 2020 18:28:34
User entered '11 Sep 2020 13:28'	System	11 Sep 2020 18:28:34

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	08 Sep 2020 19:11:21
User entered 'Day 5'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-12T12:14:08', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '7eb8fca5-2d72-400c-b9f3-2e4a16870d13'	System	12 Sep 2020 17:14:25
User entered 'None (0)'	System	12 Sep 2020 17:14:25

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-12T12:14:10', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '7eb8fca5-2d72-400c-b9f3-2e4a16870d13'	System	12 Sep 2020 17:14:25
User entered 'None (0)'	System	12 Sep 2020 17:14:25

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-12T12:14:12', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '7eb8fca5-2d72-400c-b9f3-2e4a16870d13'	System	12 Sep 2020 17:14:25
User entered 'None (0)'	System	12 Sep 2020 17:14:25

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-12T12:14:14', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '7eb8fca5-2d72-400c-b9f3-2e4a16870d13'	System	12 Sep 2020 17:14:25
User entered 'None (0)'	System	12 Sep 2020 17:14:25

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-12T12:14:16', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '7eb8fca5-2d72-400c-b9f3-2e4a16870d13'	System	12 Sep 2020 17:14:25
User entered 'None (0)'	System	12 Sep 2020 17:14:25

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-12T12:14:18', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '7eb8fca5-2d72-400c-b9f3-2e4a16870d13'	System	12 Sep 2020 17:14:25
User entered 'None (0)'	System	12 Sep 2020 17:14:25

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-12T12:14:21', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '7eb8fca5-2d72-400c-b9f3-2e4a16870d13'	System	12 Sep 2020 17:14:25
User entered 'No (N)'	System	12 Sep 2020 17:14:25

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-12T12:14:23', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '7eb8fca5-2d72-400c-b9f3-2e4a16870d13'	System	12 Sep 2020 17:14:25
User entered '12 Sep 2020 12:14'	System	12 Sep 2020 17:14:25

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	08 Sep 2020 19:11:21
User entered 'Day 6'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-13T16:16:20', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a1cc8847-420c-4a12-81b8-b3396ebb2eb7'	System	13 Sep 2020 21:16:38
User entered 'None (0)'	System	13 Sep 2020 21:16:38

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-13T16:16:22', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a1cc8847-420c-4a12-81b8-b3396ebb2eb7'	System	13 Sep 2020 21:16:38
User entered 'None (0)'	System	13 Sep 2020 21:16:38

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-13T16:16:24', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a1cc8847-420c-4a12-81b8-b3396ebb2eb7'	System	13 Sep 2020 21:16:38
User entered 'None (0)'	System	13 Sep 2020 21:16:38

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-13T16:16:26', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a1cc8847-420c-4a12-81b8-b3396ebb2eb7'	System	13 Sep 2020 21:16:38
User entered 'None (0)'	System	13 Sep 2020 21:16:38

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-13T16:16:27', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a1cc8847-420c-4a12-81b8-b3396ebb2eb7'	System	13 Sep 2020 21:16:38
User entered 'None (0)'	System	13 Sep 2020 21:16:38

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-13T16:16:29', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a1cc8847-420c-4a12-81b8-b3396ebb2eb7'	System	13 Sep 2020 21:16:38
User entered 'None (0)'	System	13 Sep 2020 21:16:38

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-13T16:16:32', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a1cc8847-420c-4a12-81b8-b3396ebb2eb7'	System	13 Sep 2020 21:16:38
User entered 'No (N)'	System	13 Sep 2020 21:16:38

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-13T16:16:34', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a1cc8847-420c-4a12-81b8-b3396ebb2eb7'	System	13 Sep 2020 21:16:38
User entered '13 Sep 2020 16:16'	System	13 Sep 2020 21:16:38

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	08 Sep 2020 19:11:21
User entered 'Day 7'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-14T15:02:34', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bd739369-1d9e-4c50-9430-9c928985ab6a'	System	14 Sep 2020 20:02:53
User entered 'None (0)'	System	14 Sep 2020 20:02:53

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-14T15:02:38', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bd739369-1d9e-4c50-9430-9c928985ab6a'	System	14 Sep 2020 20:02:53
User entered 'None (0)'	System	14 Sep 2020 20:02:53

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-14T15:02:39', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bd739369-1d9e-4c50-9430-9c928985ab6a'	System	14 Sep 2020 20:02:53
User entered 'None (0)'	System	14 Sep 2020 20:02:53

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-14T15:02:41', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bd739369-1d9e-4c50-9430-9c928985ab6a'	System	14 Sep 2020 20:02:53
User entered 'None (0)'	System	14 Sep 2020 20:02:53

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-14T15:02:42', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bd739369-1d9e-4c50-9430-9c928985ab6a'	System	14 Sep 2020 20:02:53
User entered 'None (0)'	System	14 Sep 2020 20:02:53

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-14T15:02:43', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bd739369-1d9e-4c50-9430-9c928985ab6a'	System	14 Sep 2020 20:02:53
User entered 'None (0)'	System	14 Sep 2020 20:02:53

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-14T15:02:46', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bd739369-1d9e-4c50-9430-9c928985ab6a'	System	14 Sep 2020 20:02:53
User entered 'No (N)'	System	14 Sep 2020 20:02:53

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-14T15:02:49', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bd739369-1d9e-4c50-9430-9c928985ab6a'	System	14 Sep 2020 20:02:53
User entered '14 Sep 2020 15:02'	System	14 Sep 2020 20:02:53

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 19:11:21

US3212100

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	14 Sep 2020 20:02:16
User entered 'Day 8'	System	14 Sep 2020 20:02:16

US3212100

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:47:13

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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-15T12:37:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '6d40bfdd-4d7a-455f-a428-f6080a814c84'	System	15 Sep 2020 17:37:08
User entered 'No (N)'	System	15 Sep 2020 17:37:08

US3212100

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:47:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-09-15T12:37:03', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '6d40bfdd-4d7a-455f-a428-f6080a814c84'	System	15 Sep 2020 17:37:08
User entered '15 Sep 2020 12:37'	System	15 Sep 2020 17:37:08

US3212100

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:47:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 20:02:16

US3212100

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:47:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 20:02:16

US3212100

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	18 Sep 2020 15:34:38

US3212100

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered '15 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	21 Sep 2020 15:26:54
User entered '16 Sep 2020'	Laura Ngansop Djampou (b) (4)	18 Sep 2020 15:34:38

US3212100

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Laura Ngansop Djampou (b) (4)	18 Sep 2020 15:34:38

US3212100

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	18 Sep 2020 15:34:38

US3212100

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	18 Sep 2020 15:34:28

US3212100

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'I'	System	18 Sep 2020 15:34:28

US3212100

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	24 Sep 2020 15:10:14

US3212100

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '22 Sep 2020'	(b) (4) Laura Ngansop Djampou (b) (4)	24 Sep 2020 15:10:14

US3212100

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Laura Ngansop Djampou (b) (4)	24 Sep 2020 15:10:14

US3212100

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	24 Sep 2020 15:10:14

US3212100

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	24 Sep 2020 15:10:27

US3212100

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'I'	System	24 Sep 2020 15:10:27

US3212100

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	30 Sep 2020 14:35:40

US3212100

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '29 Sep 2020'	(b) (4) Laura Ngansop Djampou (b) (4)	30 Sep 2020 14:35:40

US3212100

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Laura Ngansop Djampou (b) (4)	30 Sep 2020 14:35:40

US3212100

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	30 Sep 2020 14:35:40

US3212100

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	30 Sep 2020 14:36:16

US3212100

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'I'	System	30 Sep 2020 14:36:16

US3212100

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	06 Oct 2020 19:04:55

US3212100

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered '06 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Dec 2020 15:48:43
User entered '6 Oct 2020'	Laura Ngansop Djampou (b) (4)	06 Oct 2020 19:04:55

US3212100

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

[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 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Clinic (Clinic)'	(b) (4) Laura Ngansop Djampou (b) (4)	06 Oct 2020 19:04:55

US3212100

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'VISIT3'	System	06 Oct 2020 19:04:55

US3212100

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	06 Oct 2020 19:05:39

US3212100

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered '06 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Dec 2020 15:48:48
User entered '6 Oct 2020'	Laura Ngansop Djampou (b) (4)	06 Oct 2020 19:05:39

US3212100

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '13:01'	(b) (4) Laura Ngansop Djampou (b) (4)	06 Oct 2020 19:05:39

US3212100

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered '06 Oct 2020 13:01'	System	08 Dec 2020 15:48:48
User entered '6 Oct 2020 13:01'	System	06 Oct 2020 19:05:39

US3212100

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '97.9' F	(b) (4) Laura Ngansop Djampou (b) (4)	06 Oct 2020 19:05:39

US3212100

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Oral (Oral)'	(b) (4) Laura Ngansop Djampou (b) (4)	06 Oct 2020 19:05:39

US3212100

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	06 Oct 2020 19:05:39

US3212100

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '82'	(b) (4) Laura Ngansop Djampou (b) (4)	06 Oct 2020 19:05:39

US3212100

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'bpm'	System	06 Oct 2020 19:05:39

US3212100

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '16'	(b) (4) Laura Ngansop Djampou (b) (4)	06 Oct 2020 19:05:39

US3212100

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'breaths/min'	System	06 Oct 2020 19:05:39

US3212100

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '136'	(b) (4) Laura Ngansop Djampou (b) (4)	06 Oct 2020 19:05:39

US3212100

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'mmHg'	System	06 Oct 2020 19:05:39

US3212100

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '71'	(b) (4) Laura Ngansop Djampou (b) (4)	06 Oct 2020 19:05:39

US3212100

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'mmHg'	System	06 Oct 2020 19:05:39

US3212100

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17

US3212100

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17

US3212100

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:47:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	06 Oct 2020 19:05:47

US3212100

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:47:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered '06 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Dec 2020 15:48:53
User entered '6 Oct 2020'	Laura Ngansop Djampou (b) (4)	06 Oct 2020 19:05:47

US3212100

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:47:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	06 Oct 2020 19:06:00

US3212100

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:47:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered '06 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Dec 2020 15:48:59
User entered '6 Oct 2020'	Laura Ngansop Djampou (b) (4)	06 Oct 2020 19:06:00

US3212100

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered '13:49'	(b) (4) Laura Ngansop Djampou (b) (4)	06 Oct 2020 19:06:00

US3212100

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered '06 Oct 2020 13:49'	System	08 Dec 2020 15:48:59
User entered '6 Oct 2020 13:49'	System	06 Oct 2020 19:06:00

US3212100

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	06 Oct 2020 19:06:05

US3212100

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'I'	System	06 Oct 2020 19:06:05

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 64'	System	10 Aug 2020 16:31:34

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-10-10T07:01:58', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b0fade5b-75fe-44f4-a143-e0cbc1d85fd0'	System	10 Oct 2020 12:02:11
User entered 'No (N)'	System	10 Oct 2020 12:02:11

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Have you been exposed to someone with 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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-10-10T07:02:04', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b0fade5b-75fe-44f4-a143-e0cbc1d85fd0'	System	10 Oct 2020 12:02:11
User entered 'No (N)'	System	10 Oct 2020 12:02:11

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-10-10T07:02:07', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b0fade5b-75fe-44f4-a143-e0cbc1d85fd0'	System	10 Oct 2020 12:02:11
User entered '10 Oct 2020 07:02:07'	System	10 Oct 2020 12:02:11

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 16:31:34

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 71'	System	10 Aug 2020 16:31:34

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-10-19T23:10:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '70240cd0-1e63-4d96-b193-05b966477cd6'	System	20 Oct 2020 04:10:10
User entered 'No (N)'	System	20 Oct 2020 04:10:10

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Have you been exposed to someone with 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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-10-19T23:10:05', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '70240cd0-1e63-4d96-b193-05b966477cd6'	System	20 Oct 2020 04:10:10
User entered 'No (N)'	System	20 Oct 2020 04:10:10

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-10-19T23:10:08', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '70240cd0-1e63-4d96-b193-05b966477cd6'	System	20 Oct 2020 04:10:10
User entered '19 Oct 2020 23:10:08'	System	20 Oct 2020 04:10:10

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 16:31:34

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 78'	System	10 Aug 2020 16:31:34

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-10-24T06:24:44', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '5673044c-fd78-4d8a-9f1f-46f36804375a'	System	24 Oct 2020 11:24:56
User entered 'No (N)'	System	24 Oct 2020 11:24:56

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Have you been exposed to someone with 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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-10-24T06:24:50', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '5673044c-fd78-4d8a-9f1f-46f36804375a'	System	24 Oct 2020 11:24:56
User entered 'No (N)'	System	24 Oct 2020 11:24:56

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-10-24T06:24:53', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '5673044c-fd78-4d8a-9f1f-46f36804375a' User entered '24 Oct 2020 06:24:53'	System	24 Oct 2020 11:24:56
	System	24 Oct 2020 11:24:56

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 16:31:34

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 92'	System	10 Aug 2020 16:31:34

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-11-07T17:13:45', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '435dfdb7-efee-4e17-b891-47260b6072ba'	System	07 Nov 2020 23:13:55
User entered 'No (N)'	System	07 Nov 2020 23:13:55

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Have you been exposed to someone with 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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-11-07T17:13:49', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '435dfdb7-efee-4e17-b891-47260b6072ba'	System	07 Nov 2020 23:13:55
User entered 'No (N)'	System	07 Nov 2020 23:13:55

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-11-07T17:13:51', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '435dfdb7-efee-4e17-b891-47260b6072ba'	System	07 Nov 2020 23:13:55
User entered '07 Nov 2020 17:13:51'	System	07 Nov 2020 23:13:55

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 16:31:34

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered 'Day 99'	System	10 Aug 2020 16:31:34

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-11-14T17:01:55', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '439f25fa-82fd-4b15-8fa4-1c1779121090'	System	14 Nov 2020 23:02:04
User entered 'No (N)'	System	14 Nov 2020 23:02:04

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Have you been exposed to someone with 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 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-11-14T17:01:58', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '439f25fa-82fd-4b15-8fa4-1c1779121090'	System	14 Nov 2020 23:02:04
User entered 'No (N)'	System	14 Nov 2020 23:02:04

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-11-14T17:02:01', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '439f25fa-82fd-4b15-8fa4-1c1779121090'	System	14 Nov 2020 23:02:04
User entered '14 Nov 2020 17:02:01'	System	14 Nov 2020 23:02:04

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 16:31:34

US3212100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:05:32
Data entry locked.	System	10 Aug 2020 16:31:34
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 16:31:34

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 (7a4408d64bb91427)', Time: '2020-11-21T06:25:18', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bc033af5-5079-4869-8d58-70e30faf678b'	System	21 Nov 2020 12:26:20
User entered 'Yes (Y)'	System	21 Nov 2020 12:26:20

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Have you been exposed to someone with 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 (7a4408d64bb91427)', Time: '2020-11-21T06:25:22', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bc033af5-5079-4869-8d58-70e30faf678b'	System	21 Nov 2020 12:26:20
User entered 'No (N)'	System	21 Nov 2020 12:26:20

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-11-21T06:25:28', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bc033af5-5079-4869-8d58-70e30faf678b'	System	21 Nov 2020 12:26:20
User entered 'No (N)'	System	21 Nov 2020 12:26:20

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-11-21T06:25:41', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bc033af5-5079-4869-8d58-70e30faf678b'	System	21 Nov 2020 12:26:20
User entered 'Yes (Y)'	System	21 Nov 2020 12:26:20

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-11-21T06:26:05', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bc033af5-5079-4869-8d58-70e30faf678b'	System	21 Nov 2020 12:26:20
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Nov 2020 12:26:20

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-11-21T06:26:07', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'bc033af5-5079-4869-8d58-70e30faf678b'	System	21 Nov 2020 12:26:20
User entered '21 Nov 2020 06:26:07'	System	21 Nov 2020 12:26:20

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 (7a4408d64bb91427)', Time: '2020-11-25T17:02:24', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'd1bd4a76-6c3b-4065-b0f7-6f769f9b7ab7'	System	25 Nov 2020 23:02:35
User entered 'No (N)'	System	25 Nov 2020 23:02:35

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Have you been exposed to someone with 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 (7a4408d64bb91427)', Time: '2020-11-25T17:02:28', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'd1bd4a76-6c3b-4065-b0f7-6f769f9b7ab7'	System	25 Nov 2020 23:02:35
User entered 'No (N)'	System	25 Nov 2020 23:02:35

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-11-25T17:02:30', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'd1bd4a76-6c3b-4065-b0f7-6f769f9b7ab7'	System	25 Nov 2020 23:02:35
User entered '25 Nov 2020 17:02:30'	System	25 Nov 2020 23:02:35

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 (7a4408d64bb91427)', Time: '2020-12-02T05:23:27', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '66952b79-b947-45f5-8525-65cd1fde6b6a'	System	02 Dec 2020 11:23:54
User entered 'No (N)'	System	02 Dec 2020 11:23:54

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Have you been exposed to someone with 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 (7a4408d64bb91427)', Time: '2020-12-02T05:23:34', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '66952b79-b947-45f5-8525-65cd1fde6b6a'	System	02 Dec 2020 11:23:54
User entered 'Yes (Y)'	System	02 Dec 2020 11:23:54

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-12-02T05:23:41', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '66952b79-b947-45f5-8525-65cd1fde6b6a'	System	02 Dec 2020 11:23:54
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Dec 2020 11:23:54

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-12-02T05:23:43', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '66952b79-b947-45f5-8525-65cd1fde6b6a' User entered '02 Dec 2020 05:23:43'	System	02 Dec 2020 11:23:54
	System	02 Dec 2020 11:23:54

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 (7a4408d64bb91427)', Time: '2020-12-09T05:54:44', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '324e217f-5129-455c-a56e-98f4f042b313'	System	09 Dec 2020 11:54:50
User entered 'No (N)'	System	09 Dec 2020 11:54:50

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Have you been exposed to someone with 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 (7a4408d64bb91427)', Time: '2020-12-09T05:54:47', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '324e217f-5129-455c-a56e-98f4f042b313'	System	09 Dec 2020 11:54:50
User entered 'No (N)'	System	09 Dec 2020 11:54:50

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-12-09T05:54:49', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '324e217f-5129-455c-a56e-98f4f042b313' User entered '09 Dec 2020 05:54:49'	System	09 Dec 2020 11:54:50
	System	09 Dec 2020 11:54:50

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 (7a4408d64bb91427)', Time: '2020-12-16T03:03:23', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '9475b833-5105-4360-a2d3-6f253e541ce4'	System	16 Dec 2020 09:03:47
User entered 'Yes (Y)'	System	16 Dec 2020 09:03:47

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Have you been exposed to someone with 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 (7a4408d64bb91427)', Time: '2020-12-16T03:03:31', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '9475b833-5105-4360-a2d3-6f253e541ce4'	System	16 Dec 2020 09:03:47
User entered 'No (N)'	System	16 Dec 2020 09:03:47

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-12-16T03:03:35', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '9475b833-5105-4360-a2d3-6f253e541ce4'	System	16 Dec 2020 09:03:47
User entered 'No (N)'	System	16 Dec 2020 09:03:47

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-12-16T03:03:42', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '9475b833-5105-4360-a2d3-6f253e541ce4'	System	16 Dec 2020 09:03:47
User entered 'No (N)'	System	16 Dec 2020 09:03:47

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-12-16T03:03:45', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '9475b833-5105-4360-a2d3-6f253e541ce4'	System	16 Dec 2020 09:03:47
User entered '16 Dec 2020 03:03:45'	System	16 Dec 2020 09:03:47

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 (7a4408d64bb91427)', Time: '2020-12-30T07:32:08', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a4071d91-812d-4133-b70a-d1e6d7f74c25'	System	30 Dec 2020 13:32:43
User entered 'Yes (Y)'	System	30 Dec 2020 13:32:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Have you been exposed to someone with 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 (7a4408d64bb91427)', Time: '2020-12-30T07:32:11', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a4071d91-812d-4133-b70a-d1e6d7f74c25'	System	30 Dec 2020 13:32:43
User entered 'No (N)'	System	30 Dec 2020 13:32:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-12-30T07:32:15', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a4071d91-812d-4133-b70a-d1e6d7f74c25'	System	30 Dec 2020 13:32:43
User entered 'No (N)'	System	30 Dec 2020 13:32:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-12-30T07:32:23', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a4071d91-812d-4133-b70a-d1e6d7f74c25'	System	30 Dec 2020 13:32:43
User entered 'Yes (Y)'	System	30 Dec 2020 13:32:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-12-30T07:32:28', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a4071d91-812d-4133-b70a-d1e6d7f74c25'	System	30 Dec 2020 13:32:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Dec 2020 13:32:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2020-12-30T07:32:32', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a4071d91-812d-4133-b70a-d1e6d7f74c25'	System	30 Dec 2020 13:32:43
User entered '30 Dec 2020 07:32:32'	System	30 Dec 2020 13:32:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 (7a4408d64bb91427)', Time: '2021-01-10T19:44:33', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '3d8a8665-2d14-49e1-a235-de53400db3cf'	System	11 Jan 2021 01:44:40
User entered 'No (N)'	System	11 Jan 2021 01:44:40

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Have you been exposed to someone with 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 (7a4408d64bb91427)', Time: '2021-01-10T19:44:35', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '3d8a8665-2d14-49e1-a235-de53400db3cf'	System	11 Jan 2021 01:44:40
User entered 'No (N)'	System	11 Jan 2021 01:44:40

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-01-10T19:44:37', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '3d8a8665-2d14-49e1-a235-de53400db3cf' User entered '10 Jan 2021 19:44:37'	System	11 Jan 2021 01:44:40

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 (7a4408d64bb91427)', Time: '2021-01-13T07:18:10', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '8a407ea1-3cdc-480f-bb75-ea2c6409f3aa'	System	13 Jan 2021 13:18:26
User entered 'No (N)'	System	13 Jan 2021 13:18:26

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Have you been exposed to someone with 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 (7a4408d64bb91427)', Time: '2021-01-13T07:18:16', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '8a407ea1-3cdc-480f-bb75-ea2c6409f3aa'	System	13 Jan 2021 13:18:26
User entered 'No (N)'	System	13 Jan 2021 13:18:26

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-01-13T07:18:19', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '8a407ea1-3cdc-480f-bb75-ea2c6409f3aa'	System	13 Jan 2021 13:18:26
User entered '13 Jan 2021 07:18:19'	System	13 Jan 2021 13:18:26

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 (7a4408d64bb91427)', Time: '2021-01-20T03:27:50', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b6250e1a-3d4c-4f4d-b46d-8433d9f9bdf7'	System	20 Jan 2021 09:27:58
User entered 'No (N)'	System	20 Jan 2021 09:27:58

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Have you been exposed to someone with 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 (7a4408d64bb91427)', Time: '2021-01-20T03:27:53', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b6250e1a-3d4c-4f4d-b46d-8433d9f9bdf7'	System	20 Jan 2021 09:27:58
User entered 'No (N)'	System	20 Jan 2021 09:27:58

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-01-20T03:27:55', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b6250e1a-3d4c-4f4d-b46d-8433d9f9bdf7'	System	20 Jan 2021 09:27:58
User entered '20 Jan 2021 03:27:55'	System	20 Jan 2021 09:27:58

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 (7a4408d64bb91427)', Time: '2021-01-28T06:38:51', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'c79d37c2-c689-4a78-a3ef-ae4cc8a4197a'	System	28 Jan 2021 12:39:02
User entered 'No (N)'	System	28 Jan 2021 12:39:02

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Have you been exposed to someone with 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 (7a4408d64bb91427)', Time: '2021-01-28T06:38:56', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'c79d37c2-c689-4a78-a3ef-ae4cc8a4197a'	System	28 Jan 2021 12:39:02
User entered 'No (N)'	System	28 Jan 2021 12:39:02

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-01-28T06:38:59', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'c79d37c2-c689-4a78-a3ef-ae4cc8a4197a' User entered '28 Jan 2021 06:38:59'	System	28 Jan 2021 12:39:02
	System	28 Jan 2021 12:39:02

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 (7a4408d64bb91427)', Time: '2021-02-03T06:05:48', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a6d597b2-869e-4dd8-857e-90bd8ad9b34b'	System	03 Feb 2021 12:05:56
User entered 'No (N)'	System	03 Feb 2021 12:05:56

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Have you been exposed to someone with 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 (7a4408d64bb91427)', Time: '2021-02-03T06:05:51', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a6d597b2-869e-4dd8-857e-90bd8ad9b34b'	System	03 Feb 2021 12:05:56
User entered 'No (N)'	System	03 Feb 2021 12:05:56

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-02-03T06:05:54', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a6d597b2-869e-4dd8-857e-90bd8ad9b34b'	System	03 Feb 2021 12:05:56
User entered '03 Feb 2021 06:05:54'	System	03 Feb 2021 12:05:56

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 (7a4408d64bb91427)', Time: '2021-02-10T06:10:48', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'de9bda1c-4877-49a0-a947-c64c4827e931'	System	10 Feb 2021 12:10:54
User entered 'No (N)'	System	10 Feb 2021 12:10:54

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Have you been exposed to someone with 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 (7a4408d64bb91427)', Time: '2021-02-10T06:10:51', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'de9bda1c-4877-49a0-a947-c64c4827e931'	System	10 Feb 2021 12:10:54
User entered 'No (N)'	System	10 Feb 2021 12:10:54

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-02-10T06:10:53', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'de9bda1c-4877-49a0-a947-c64c4827e931' User entered '10 Feb 2021 06:10:53'	System	10 Feb 2021 12:10:54
	System	10 Feb 2021 12:10:54

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 (7a4408d64bb91427)', Time: '2021-02-18T08:24:51', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'd04373db-9d2d-4513-81a6-82e68435f67a'	System	18 Feb 2021 14:25:09
User entered 'No (N)'	System	18 Feb 2021 14:25:09

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Have you been exposed to someone with 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 (7a4408d64bb91427)', Time: '2021-02-18T08:24:54', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'd04373db-9d2d-4513-81a6-82e68435f67a'	System	18 Feb 2021 14:25:09
User entered 'No (N)'	System	18 Feb 2021 14:25:09

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-02-18T08:24:56', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'd04373db-9d2d-4513-81a6-82e68435f67a'	System	18 Feb 2021 14:25:09
User entered '18 Feb 2021 08:24:56'	System	18 Feb 2021 14:25:09

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 (7a4408d64bb91427)', Time: '2021-02-24T06:36:26-06:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b16e49d6-972e-450f-a5ae-ff0110213598'	System	24 Feb 2021 12:36:35
User entered 'No (N)'	System	24 Feb 2021 12:36:35

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Have you been exposed to someone with 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 (7a4408d64bb91427)', Time: '2021-02-24T06:36:28-06:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b16e49d6-972e-450f-a5ae-ff0110213598'	System	24 Feb 2021 12:36:35
User entered 'No (N)'	System	24 Feb 2021 12:36:35

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-02-24T06:36:30-06:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b16e49d6-972e-450f-a5ae-ff0110213598'	System	24 Feb 2021 12:36:35
User entered '24 Feb 2021 06:36:30'	System	24 Feb 2021 12:36:35

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 (7a4408d64bb91427)', Time: '2021-03-03T05:16:48-06:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '06207aee-710b-42bd-a58a-a2de4ce6e114'	System	03 Mar 2021 11:16:58
User entered 'No (N)'	System	03 Mar 2021 11:16:58

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Have you been exposed to someone with 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 (7a4408d64bb91427)', Time: '2021-03-03T05:16:52-06:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '06207aee-710b-42bd-a58a-a2de4ce6e114'	System	03 Mar 2021 11:16:58
User entered 'No (N)'	System	03 Mar 2021 11:16:58

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-03-03T05:16:54-06:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '06207aee-710b-42bd-a58a-a2de4ce6e114'	System	03 Mar 2021 11:16:58
User entered '03 Mar 2021 05:16:54'	System	03 Mar 2021 11:16:58

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 (7a4408d64bb91427)', Time: '2021-03-10T06:04:03-06:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'e282da2f-d6b6-4a4b-8f7b-54fcc51cc672'	System	10 Mar 2021 12:04:14
User entered 'No (N)'	System	10 Mar 2021 12:04:14

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Have you been exposed to someone with 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 (7a4408d64bb91427)', Time: '2021-03-10T06:04:06-06:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'e282da2f-d6b6-4a4b-8f7b-54fcc51cc672'	System	10 Mar 2021 12:04:14
User entered 'No (N)'	System	10 Mar 2021 12:04:14

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-03-10T06:04:08-06:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'e282da2f-d6b6-4a4b-8f7b-54fcc51cc672'	System	10 Mar 2021 12:04:14
User entered '10 Mar 2021 06:04:08'	System	10 Mar 2021 12:04:14

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 (7a4408d64bb91427)', Time: '2021-03-17T09:46:59-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '585231b5-f627-41d7-a6ae-a88a9fc08002'	System	17 Mar 2021 14:47:08
User entered 'No (N)'	System	17 Mar 2021 14:47:08

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Have you been exposed to someone with 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 (7a4408d64bb91427)', Time: '2021-03-17T09:47:02-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '585231b5-f627-41d7-a6ae-a88a9fc08002'	System	17 Mar 2021 14:47:08
User entered 'No (N)'	System	17 Mar 2021 14:47:08

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-03-17T09:47:05-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '585231b5-f627-41d7-a6ae-a88a9fc08002'	System	17 Mar 2021 14:47:08
User entered '17 Mar 2021 09:47:05'	System	17 Mar 2021 14:47:08

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 (7a4408d64bb91427)', Time: '2021-03-24T09:55:41-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '1d6b9176-b7e6-4614-9f11-a73c8d8eba13'	System	24 Mar 2021 14:55:45
User entered 'No (N)'	System	24 Mar 2021 14:55:45

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Have you been exposed to someone with 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 (7a4408d64bb91427)', Time: '2021-03-24T09:55:42-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '1d6b9176-b7e6-4614-9f11-a73c8d8eba13'	System	24 Mar 2021 14:55:45
User entered 'No (N)'	System	24 Mar 2021 14:55:45

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-03-24T09:55:44-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '1d6b9176-b7e6-4614-9f11-a73c8d8eba13' User entered '24 Mar 2021 09:55:44'	System	24 Mar 2021 14:55:45
	System	24 Mar 2021 14:55:45

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 (7a4408d64bb91427)', Time: '2021-03-31T06:11:03-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a45960cd-f8b6-46ae-b24b-981ba94ed034'	System	31 Mar 2021 11:11:14
User entered 'No (N)'	System	31 Mar 2021 11:11:14

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Have you been exposed to someone with 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 (7a4408d64bb91427)', Time: '2021-03-31T06:11:05-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a45960cd-f8b6-46ae-b24b-981ba94ed034'	System	31 Mar 2021 11:11:14
User entered 'No (N)'	System	31 Mar 2021 11:11:14

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-03-31T06:11:08-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'a45960cd-f8b6-46ae-b24b-981ba94ed034' User entered '31 Mar 2021 06:11:08'	System	31 Mar 2021 11:11:14
	System	31 Mar 2021 11:11:14

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 (7a4408d64bb91427)', Time: '2021-04-07T07:26:30-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0900ae51-eb43-4964-adb1-81e073dbf198'	System	07 Apr 2021 12:27:43
User entered 'Yes (Y)'	System	07 Apr 2021 12:27:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Have you been exposed to someone with 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 (7a4408d64bb91427)', Time: '2021-04-07T07:26:37-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0900ae51-eb43-4964-adb1-81e073dbf198'	System	07 Apr 2021 12:27:43
User entered 'No (N)'	System	07 Apr 2021 12:27:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-07T07:26:54-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0900ae51-eb43-4964-adb1-81e073dbf198'	System	07 Apr 2021 12:27:43
User entered 'Yes (Y)'	System	07 Apr 2021 12:27:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-07T07:27:09-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0900ae51-eb43-4964-adb1-81e073dbf198' User entered '0'	System	07 Apr 2021 12:27:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-07T07:27:09-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0900ae51-eb43-4964-adb1-81e073dbf198'	System	07 Apr 2021 12:27:43
User entered '0'	System	07 Apr 2021 12:27:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-07T07:27:09-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0900ae51-eb43-4964-adb1-81e073dbf198'	System	07 Apr 2021 12:27:43
User entered '1'	System	07 Apr 2021 12:27:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-07T07:27:09-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0900ae51-eb43-4964-adb1-81e073dbf198' User entered '0'	System	07 Apr 2021 12:27:43
	System	07 Apr 2021 12:27:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-07T07:27:09-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0900ae51-eb43-4964-adb1-81e073dbf198' User entered '0'	System	07 Apr 2021 12:27:43
	System	07 Apr 2021 12:27:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-07T07:27:09-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0900ae51-eb43-4964-adb1-81e073dbf198' User entered '0'	System	07 Apr 2021 12:27:43
	System	07 Apr 2021 12:27:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-07T07:27:09-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0900ae51-eb43-4964-adb1-81e073dbf198'	System	07 Apr 2021 12:27:43
User entered '0'	System	07 Apr 2021 12:27:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-07T07:27:09-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0900ae51-eb43-4964-adb1-81e073dbf198' User entered '0'	System	07 Apr 2021 12:27:43
	System	07 Apr 2021 12:27:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-07T07:27:09-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0900ae51-eb43-4964-adb1-81e073dbf198' User entered '0'	System	07 Apr 2021 12:27:43
	System	07 Apr 2021 12:27:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-07T07:27:09-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0900ae51-eb43-4964-adb1-81e073dbf198'	System	07 Apr 2021 12:27:43
User entered '0'	System	07 Apr 2021 12:27:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-07T07:27:09-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0900ae51-eb43-4964-adb1-81e073dbf198' User entered '0'	System	07 Apr 2021 12:27:43
	System	07 Apr 2021 12:27:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-07T07:27:09-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0900ae51-eb43-4964-adb1-81e073dbf198' User entered '0'	System	07 Apr 2021 12:27:43
	System	07 Apr 2021 12:27:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-07T07:27:09-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0900ae51-eb43-4964-adb1-81e073dbf198'	System	07 Apr 2021 12:27:43
User entered '1'	System	07 Apr 2021 12:27:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-07T07:27:09-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0900ae51-eb43-4964-adb1-81e073dbf198'	System	07 Apr 2021 12:27:43
User entered '1'	System	07 Apr 2021 12:27:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-07T07:27:09-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0900ae51-eb43-4964-adb1-81e073dbf198' User entered '0'	System	07 Apr 2021 12:27:43
	System	07 Apr 2021 12:27:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-07T07:27:09-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0900ae51-eb43-4964-adb1-81e073dbf198' User entered '0'	System	07 Apr 2021 12:27:43
	System	07 Apr 2021 12:27:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-07T07:27:09-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0900ae51-eb43-4964-adb1-81e073dbf198' User entered '0'	System	07 Apr 2021 12:27:43
	System	07 Apr 2021 12:27:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-07T07:27:15-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0900ae51-eb43-4964-adb1-81e073dbf198'	System	07 Apr 2021 12:27:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Apr 2021 12:27:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-07T07:27:24-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0900ae51-eb43-4964-adb1-81e073dbf198'	System	07 Apr 2021 12:27:43
User entered 'No (N)'	System	07 Apr 2021 12:27:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-07T07:27:26-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '0900ae51-eb43-4964-adb1-81e073dbf198'	System	07 Apr 2021 12:27:43
User entered '07 Apr 2021 07:27:26'	System	07 Apr 2021 12:27:43

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 (7a4408d64bb91427)', Time: '2021-04-14T07:11:27-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b5840f13-4d42-4f73-bd1b-5c9c44d8ab1f' User entered 'Yes (Y)'	System	14 Apr 2021 16:28:41
	System	14 Apr 2021 16:28:41

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Have you been exposed to someone with 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 (7a4408d64bb91427)', Time: '2021-04-14T07:11:31-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b5840f13-4d42-4f73-bd1b-5c9c44d8ab1f' User entered 'No (N)'	System	14 Apr 2021 16:28:41
	System	14 Apr 2021 16:28:41

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-14T07:11:35-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b5840f13-4d42-4f73-bd1b-5c9c44d8ab1f' User entered 'No (N)'	System	14 Apr 2021 16:28:41
	System	14 Apr 2021 16:28:41

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-14T07:11:39-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b5840f13-4d42-4f73-bd1b-5c9c44d8ab1f' User entered 'No (N)'	System	14 Apr 2021 16:28:41
	System	14 Apr 2021 16:28:41

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-14T07:11:41-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: 'b5840f13-4d42-4f73-bd1b-5c9c44d8ab1f' User entered '14 Apr 2021 07:11:41'	System	14 Apr 2021 16:28:41
	System	14 Apr 2021 16:28:41

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 (7a4408d64bb91427)', Time: '2021-04-21T05:13:14-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '5f8635df-7d68-4403-8023-95ca0ed7c0d4'	System	21 Apr 2021 10:13:24
User entered 'No (N)'	System	21 Apr 2021 10:13:24

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Have you been exposed to someone with 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 (7a4408d64bb91427)', Time: '2021-04-21T05:13:17-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '5f8635df-7d68-4403-8023-95ca0ed7c0d4'	System	21 Apr 2021 10:13:24
User entered 'No (N)'	System	21 Apr 2021 10:13:24

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-21T05:13:18-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '5f8635df-7d68-4403-8023-95ca0ed7c0d4'	System	21 Apr 2021 10:13:24
User entered '21 Apr 2021 05:13:18'	System	21 Apr 2021 10:13:24

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[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 (7a4408d64bb91427)', Time: '2021-04-28T05:22:11-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '2b159b60-319a-4488-b85f-bd496e220cd8'	System	29 Apr 2021 03:16:51
User entered 'No (N)'	System	29 Apr 2021 03:16:51

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

Have you been exposed to someone with 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 (7a4408d64bb91427)', Time: '2021-04-28T05:22:15-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '2b159b60-319a-4488-b85f-bd496e220cd8'	System	29 Apr 2021 03:16:51
User entered 'No (N)'	System	29 Apr 2021 03:16:51

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-04-28T05:22:17-05:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '2b159b60-319a-4488-b85f-bd496e220cd8'	System	29 Apr 2021 03:16:51
User entered '28 Apr 2021 05:22:17'	System	29 Apr 2021 03:16:51

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 17:10:32

US3212100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:47:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:32
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 17:10:32

US3212100

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:47:13

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 07:59:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-03-01T17:54:37-06:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '03805805-7f3d-4eac-a385-2074edddf483'	System	01 Mar 2021 23:54:43
User entered 'No (N)'	System	01 Mar 2021 23:54:43

US3212100

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:47:13

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:59:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7a4408d64bb91427)', Time: '2021-03-01T17:54:40-06:00', User OID: 'PatientReportedOutcome (US3212100)', ODM File OID: '03805805-7f3d-4eac-a385-2074edddf483'	System	01 Mar 2021 23:54:43
User entered '01 Mar 2021 17:54:40'	System	01 Mar 2021 23:54:43

US3212100

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	03 Nov 2020 15:07:20

US3212100

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
	(b) (4)	
User entered '02 Nov 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Dec 2020 15:49:09
User entered '2 Nov 2020'	Laura Ngansop Djampou (b) (4)	03 Nov 2020 15:07:20

US3212100

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Laura Ngansop Djampou (b) (4)	03 Nov 2020 15:07:20

US3212100

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	03 Nov 2020 15:07:20

US3212100

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 18:14:00
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	03 Nov 2020 15:07:27

US3212100

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:03:17
User entered 'I'	System	03 Nov 2020 15:07:27

US3212100

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Dec 2020 15:46:06

US3212100

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '07 Dec 2020'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Dec 2020 15:46:06

US3212100

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Dec 2020 15:46:06

US3212100

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	08 Dec 2020 15:46:06

US3212100

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Dec 2020 15:46:42

US3212100

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User entered 'I'	System	08 Dec 2020 15:46:42

US3212100

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	07 Jan 2021 16:11:17

US3212100

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '06 Jan 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	07 Jan 2021 16:11:17

US3212100

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Laura Ngansop Djampou (b) (4)	07 Jan 2021 16:11:17

US3212100

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	07 Jan 2021 16:11:17

US3212100

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	07 Jan 2021 16:11:06

US3212100

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User entered 'I'	System	07 Jan 2021 16:11:06

US3212100

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Feb 2021 18:35:01

US3212100

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '04 Feb 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Feb 2021 18:35:01

US3212100

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Feb 2021 18:35:01

US3212100

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	08 Feb 2021 18:35:01

US3212100

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	08 Feb 2021 18:35:06

US3212100

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User entered 'I'	System	08 Feb 2021 18:35:06

US3212100

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	10 Mar 2021 14:57:17

US3212100

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '09 Mar 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	10 Mar 2021 14:57:17

US3212100

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

[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 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Clinic (Clinic)'	(b) (4) Laura Ngansop Djampou (b) (4)	10 Mar 2021 14:57:17

US3212100

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User entered 'VISIT4'	System	10 Mar 2021 14:57:17

US3212100

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:52:33

US3212100

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:52:33

US3212100

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '12:22'	(b) (4), (b) (6)	30 Mar 2021 18:52:33

US3212100

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User entered '09 Mar 2021 12:22'	System	30 Mar 2021 18:52:33

US3212100

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '97.4' F	(b) (4), (b) (6)	30 Mar 2021 18:52:33

US3212100

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:52:33

US3212100

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:52:33

US3212100

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '76'	(b) (4), (b) (6)	30 Mar 2021 18:52:33

US3212100

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User entered 'bpm'	System	30 Mar 2021 18:52:33

US3212100

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '14'	(b) (4), (b) (6)	30 Mar 2021 18:52:33

US3212100

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User entered 'breaths/min'	System	30 Mar 2021 18:52:33

US3212100

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '130'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:52:33

US3212100

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User entered 'mmHg'	System	30 Mar 2021 18:52:33

US3212100

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '72'	(b) (4), (b) (6)	30 Mar 2021 18:52:33

US3212100

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User entered 'mmHg'	System	30 Mar 2021 18:52:33

US3212100

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05

US3212100

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05

US3212100

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:47:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	10 Mar 2021 14:57:28

US3212100

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:47:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '09 Mar 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	10 Mar 2021 14:57:28

US3212100

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:47:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	10 Mar 2021 14:57:39

US3212100

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:47:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '9 Mar 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	10 Mar 2021 14:57:39

US3212100

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '12:45'	(b) (4) Laura Ngansop Djampou (b) (4)	10 Mar 2021 14:57:39

US3212100

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User entered '9 Mar 2021 12:45'	System	10 Mar 2021 14:57:39

US3212100

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	10 Mar 2021 14:59:15

US3212100

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:47:05
User entered 'I'	System	10 Mar 2021 14:59:15

US3212100

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	22 Apr 2021 17:37:40

US3212100

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
User entered '05 Apr 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	22 Apr 2021 17:37:40

US3212100

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Laura Ngansop Djampou (b) (4)	22 Apr 2021 17:37:40

US3212100

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	22 Apr 2021 17:37:40

US3212100

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	22 Apr 2021 17:37:46

US3212100

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Apr 2021 17:37:46

US3212100

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	03 May 2021 18:29:35
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	03 May 2021 18:02:50

US3212100

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	03 May 2021 18:29:35
User entered '3 May 2021'	(b) (4), (b) (6) (b) (4)	03 May 2021 18:02:50

US3212100

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	03 May 2021 18:29:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6) (b) (4), (b) (6)	03 May 2021 18:02:50

US3212100

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:47:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	03 May 2021 18:29:35
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 May 2021 18:02:50

US3212100

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	03 May 2021 18:29:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 18:02:36

US3212100

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:47:13

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 18:02:36

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:47:13

[Date of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered '8 Apr 2021'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:04:57
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:47:13

[Time of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered '13:30'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:04:57
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:47:13

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '8 Apr 2021 13:30'	System	09 Apr 2021 16:04:57

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:47:13

[Type of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:04:57

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:47:13

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'Yes (Y)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:04:57
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:47:13

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'Day 1 (Day 1)'	Heather Leary (b) (4)	09 Apr 2021 16:06:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:47:13

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered '5 Apr 2021'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:47:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered '0'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:47:13

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered missing code ND - Not Done.	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:37

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:47:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	09 Apr 2021 16:06:37

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:47:13

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered missing code ND - Not Done.	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:37

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:47:13

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:47:13

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:47:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:47:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:47:13

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:47:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:37

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:47:13

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:47:13

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:47:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:47:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:47:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'Moderate (Moderate)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:47:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'Moderate (Moderate)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:47:13

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:47:13

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:47:13

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:37

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:47:13

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:47:13

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'Day 2 (Day 2)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:47

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:47:13

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered '6 Apr 2021'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:47
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:47:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'I'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:47
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:47:13

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:06:47

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:47:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 16:06:47

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:47:13

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:06:47

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:47:13

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:06:47

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:47:13

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered empty.	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:47
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:47:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered empty.	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:47
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:47:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered empty.	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:47
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:47:13

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered empty.	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:47
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:47:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered empty.	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:47
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:47:13

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:06:47

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:47:13

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered empty.	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:47
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:47:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:06:47

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:47:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered empty.	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:47
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:47:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:06:47

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:47:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered empty.	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:47
	(b) (4)	

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:47:13

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered empty.	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:47
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:47:13

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered empty.	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:47
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:47:13

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:06:47

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:47:13

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered empty.	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:47
	(b) (4)	

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:47:13

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'Day 3 (Day 3)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:58
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:47:13

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered '7 Apr 2021'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:58

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:47:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'I'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:58
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:47:13

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:06:58

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:47:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 16:06:58

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:47:13

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:06:58

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:47:13

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:06:58

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:47:13

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:06:58

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:47:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:06:58

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:47:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered empty.	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:58
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:47:13

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:06:58

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:47:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered empty.	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:58
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:47:13

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered empty.	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:58
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:47:13

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:06:58

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:47:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:06:58

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:47:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:06:58

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:47:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered empty.	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:58
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:47:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered empty.	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:58
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:47:13

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered empty.	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:58
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:47:13

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:06:58

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:47:13

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:06:58

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:47:13

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered empty.	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:06:58
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:47:13

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'Day 4 (Day 4)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:09
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:47:13

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered '8 Apr 2021'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:09
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:47:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered '0'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:09
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:47:13

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered '100'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:09
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:47:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	09 Apr 2021 16:08:09

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:47:13

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered '98.9' F	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:09

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:47:13

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:09
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:47:13

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:09
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:47:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:09
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:47:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:09
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:47:13

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:09
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:47:13

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:09
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:47:13

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:09
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:47:13

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:09
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:47:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:09
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:47:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:09
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:47:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'Moderate (Moderate)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:09
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:47:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'Moderate (Moderate)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:09
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:47:13

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:09
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:47:13

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:09
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:47:13

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:09
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:47:13

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:09
	(b) (4)	

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:47:13

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'Day 5 (Day 5)'	Afifah Ayub (b) (4)	13 Apr 2021 15:59:37
	(b) (4)	

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:47:13

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered '09 Apr 2021'	Afifah Ayub (b) (4)	13 Apr 2021 15:59:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:47:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered '0'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 15:59:37

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:47:13

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered '100'	Afifah Ayub (b) (4)	13 Apr 2021 15:59:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:47:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	13 Apr 2021 15:59:37

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:47:13

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered '98.5' F	Afifah Ayub (b) (4)	13 Apr 2021 15:59:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:47:13

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 15:59:37

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:47:13

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	13 Apr 2021 15:59:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:47:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 15:59:37

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:47:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	13 Apr 2021 15:59:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:47:13

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	13 Apr 2021 15:59:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:47:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 15:59:37

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:47:13

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 15:59:37

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:47:13

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	13 Apr 2021 15:59:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:47:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 15:59:37

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:47:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 15:59:37

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:47:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'Moderate (Moderate)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 15:59:37

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:47:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'Moderate (Moderate)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 15:59:37

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:47:13

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	13 Apr 2021 15:59:37
	(b) (4)	

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:47:13

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	13 Apr 2021 15:59:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:47:13

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	13 Apr 2021 15:59:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:47:13

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	13 Apr 2021 15:59:37
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:47:13

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'Day 6 (Day 6)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:02:50

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:47:13

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered '10 Apr 2021'	Afifah Ayub (b) (4)	13 Apr 2021 16:02:50
	(b) (4)	

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:47:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered '0'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:02:50

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:47:13

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered '100'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:02:50

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:47:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	13 Apr 2021 16:02:50

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:47:13

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered '98.2' F	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:02:50

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:47:13

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:02:50

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:47:13

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:02:50

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:47:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4)	13 Apr 2021 16:02:50
	(b) (4)	

US3212100

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:47:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4)	13 Apr 2021 16:02:50
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:47:13

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	13 Apr 2021 16:02:50
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:47:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:02:50

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:47:13

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	13 Apr 2021 16:02:50
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:47:13

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	13 Apr 2021 16:02:50
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:47:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:02:50

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:47:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:02:50

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:47:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:02:50

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:47:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	13 Apr 2021 16:02:50
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:47:13

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:02:50

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:47:13

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:02:50

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:47:13

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	13 Apr 2021 16:02:50
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:47:13

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:02:50

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:47:13

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'Day 7 (Day 7)'	Afifah Ayub (b) (4)	13 Apr 2021 16:04:07
	(b) (4)	

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[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered '11 Apr 2021'	(b) (4) Afifah Ayub (b) (4)	13 Apr 2021 16:04:07
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:47:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered '0'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:04:07

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:47:13

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered '100'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:04:07

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Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:47:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	13 Apr 2021 16:04:07

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:47:13

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered '97.8' F	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:04:07

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:47:13

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:04:07

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:47:13

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	13 Apr 2021 16:04:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:47:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:04:07

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:47:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:04:07

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:47:13

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:04:07

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:47:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:04:07

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:47:13

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4)	13 Apr 2021 16:04:07
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:47:13

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	13 Apr 2021 16:04:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:47:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4)	13 Apr 2021 16:04:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:47:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:04:07

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:47:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	13 Apr 2021 16:04:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:47:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	13 Apr 2021 16:04:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:47:13

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	13 Apr 2021 16:04:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:47:13

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:04:07

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:47:13

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:04:07

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:47:13

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	13 Apr 2021 16:04:07
	(b) (4)	

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[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'Day 8 (Day 8)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:12

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[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered '12 Apr 2021'	(b) (4) Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:12

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:47:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered '0'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:12

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:47:13

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered '100'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:12

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:47:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	13 Apr 2021 16:05:12

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:47:13

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered '97.7' F	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:12

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:47:13

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:12

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:47:13

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:12

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:47:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:12

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:47:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:12

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:47:13

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	13 Apr 2021 16:05:12
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:47:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:12

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:47:13

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:12

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:47:13

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	13 Apr 2021 16:05:12
	(b) (4)	

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:47:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	13 Apr 2021 16:05:12
	(b) (4)	

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Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:47:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:12

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:47:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	13 Apr 2021 16:05:12
	(b) (4)	

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Form: Symptom Log (8)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	13 Apr 2021 16:05:12
	(b) (4)	

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Form: Symptom Log (8)

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[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	13 Apr 2021 16:05:12
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:47:13

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	13 Apr 2021 16:05:12
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:47:13

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	13 Apr 2021 16:05:12
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:47:13

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	13 Apr 2021 16:05:12
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:47:13

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
	(b) (4)	
User entered 'Day 9 (Day 9)'	Afifah Ayub (b) (4)	21 Apr 2021 19:24:49
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:47:13

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
	(b) (4)	
User entered '13 Apr 2021'	Afifah Ayub (b) (4)	21 Apr 2021 19:24:49
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:47:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:26:28
User entered '0'	Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:24:49

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:47:13

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:26:28
User entered '100'	Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:24:49

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:47:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Apr 2021 19:24:49

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:47:13

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
	(b) (4)	
User entered '97.1' F	Afifah Ayub (b) (4)	21 Apr 2021 19:24:49
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:47:13

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:26:28
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:24:49

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:47:13

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	21 Apr 2021 19:24:49
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:47:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:26:28
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:24:49

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:47:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4)	21 Apr 2021 19:24:49
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:47:13

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:26:28
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:24:49

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:47:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	21 Apr 2021 19:24:49
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:47:13

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:24:49

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:47:13

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	21 Apr 2021 19:24:49
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:47:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:26:28
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:24:49

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:47:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:26:28
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:24:49

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:47:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:24:49

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:47:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
User entered 'None (None)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:24:49

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:47:13

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	21 Apr 2021 19:24:49
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:47:13

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:26:28
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:24:49

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:47:13

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	21 Apr 2021 19:24:49
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:47:13

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
	(b) (4)	
User entered 'None (None)'	Afifah Ayub (b) (4)	21 Apr 2021 19:24:49
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:47:13

[Date of Visit](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered '8 Apr 2021'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:27
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:47:13

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'Yes (Y)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:27
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:47:13

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User closed query 'Per CDM: Response noted, Update data once available. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 09:26:17
Query 'Per CDM: Response noted, Update data once available. Thank you' answered with 'updated per lab results' (Site from DM).	Heather Leary (b) (4) (b) (4)	14 Apr 2021 14:30:29
User entered 'No (N)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	14 Apr 2021 14:30:05
User opened query 'Per CDM: Response noted, Update data once available. Thank you' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 12:19:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Apr 2021 12:16:21
Query 'Data is required. Please complete.' answered with 'will update as information is available' (Site from System).	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:08:37
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 16:08:27
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:08:27

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:47:13

[Date of Test](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered '8 Apr 2021'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:27
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:47:13

[Type of Test Performed](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:27

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:47:13

[Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:08:27

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:47:13

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'No (N)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:08:27
	(b) (4)	

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:47:13

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:08:27

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:47:13

[CLIA Certified?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:08:27

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:47:13

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Apr 2021 14:30:05

US3212100

Folder: Covid-19 Assessment 08 Apr 2021

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:47:13

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'No (N)'	Afifah Ayub (b) (4)	13 Apr 2021 15:57:58
	(b) (4)	

US3212100

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:47:13

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:45

US3212100

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:47:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:45

US3212100

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:47:13

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered '10 Apr 2021'	Afifah Ayub (b) (4)	13 Apr 2021 16:05:45
	(b) (4)	

US3212100

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:47:13

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:45

US3212100

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:47:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:45

US3212100

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:47:13

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered '12 Apr 2021'	(b) (4) Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:45

US3212100

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:47:13

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:45

US3212100

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:47:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
Signature has been broken.	(b) (4)	
	Afifah Ayub (b) (4)	21 Apr 2021 19:22:31
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Afifah Ayub (b) (4)	21 Apr 2021 19:22:31
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'No (N)'	Afifah Ayub (b) (4)	13 Apr 2021 16:05:45
	(b) (4)	

US3212100

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:47:13

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:45

US3212100

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:47:13

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:45

US3212100

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:47:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
	(b) (4)	
Signature has been broken.	Afifah Ayub (b) (4)	21 Apr 2021 19:22:31
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Afifah Ayub (b) (4)	21 Apr 2021 19:22:31
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'No (N)'	Afifah Ayub (b) (4)	13 Apr 2021 16:05:45
	(b) (4)	

US3212100

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:47:13

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:45

US3212100

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:47:13

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:45

US3212100

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:47:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
	(b) (4)	
Signature has been broken.	Afifah Ayub (b) (4)	21 Apr 2021 19:23:28
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Afifah Ayub (b) (4)	21 Apr 2021 19:23:28
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'No (N)'	Afifah Ayub (b) (4)	13 Apr 2021 16:05:45
	(b) (4)	

US3212100

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:47:13

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:45

US3212100

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:47:13

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:45

US3212100

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:47:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
	(b) (4)	
Signature has been broken.	Afifah Ayub (b) (4)	21 Apr 2021 19:22:31
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Afifah Ayub (b) (4)	21 Apr 2021 19:22:31
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'No (N)'	Afifah Ayub (b) (4)	13 Apr 2021 16:05:45
	(b) (4)	

US3212100

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:47:13

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:45

US3212100

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:47:13

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:45

US3212100

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:47:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
	(b) (4)	
Signature has been broken.	Afifah Ayub (b) (4)	21 Apr 2021 19:22:31
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Afifah Ayub (b) (4)	21 Apr 2021 19:22:31
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered 'No (N)'	Afifah Ayub (b) (4)	13 Apr 2021 16:05:45
	(b) (4)	

US3212100

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:47:13

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Afifah Ayub (b) (4) (b) (4)	13 Apr 2021 16:05:45

US3212100

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'Yes (Y)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:11:02
	(b) (4)	

US3212100

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered '8 Apr 2021'	Heather Leary (b) (4)	09 Apr 2021 16:11:02
	(b) (4)	

US3212100

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'Clinic (Clinic)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:11:02
	(b) (4)	

US3212100

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	09 Apr 2021 16:11:02

US3212100

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:11:58

US3212100

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered '8 Apr 2021'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:11:58
	(b) (4)	

US3212100

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered '13:25'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:11:58

US3212100

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User entered '8 Apr 2021 13:25'	System	09 Apr 2021 16:11:58

US3212100

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered missing code ND - Not Done.	(b) (4)	
	Heather Leary (b) (4)	09 Apr 2021 16:11:58
DataPoint set to visible.	(b) (4)	
	System	09 Apr 2021 16:11:02

US3212100

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered missing code ND - Not Done.	(b) (4)	
	Heather Leary (b) (4)	09 Apr 2021 16:11:58
DataPoint set to visible.	(b) (4)	
	System	09 Apr 2021 16:11:02

US3212100

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered '98.9' F	Heather Leary (b) (4)	09 Apr 2021 16:11:58
	(b) (4)	

US3212100

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'Oral (Oral)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:11:58
	(b) (4)	

US3212100

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:11:58

US3212100

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
	(b) (4)	
User entered '86'	Heather Leary (b) (4)	09 Apr 2021 16:11:58
	(b) (4)	

US3212100

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Apr 2021 16:11:58

US3212100

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered '15'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:11:58
	(b) (4)	

US3212100

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Apr 2021 16:11:58

US3212100

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered '128'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:11:58
	(b) (4)	

US3212100

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 16:11:58

US3212100

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered '71'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:11:58
	(b) (4)	

US3212100

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 16:11:58

US3212100

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:47:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered 'Yes (Y)'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:12:16
	(b) (4)	

US3212100

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:47:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:08:46
User entered '8 Apr 2021'	(b) (4) Heather Leary (b) (4)	09 Apr 2021 16:12:16
	(b) (4)	

US3212100

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:47:13

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:12:27

US3212100

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:47:13

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:08:46
User entered '8 Apr 2021'	Heather Leary (b) (4) (b) (4)	09 Apr 2021 16:12:27

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:26:28
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:22:41

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:26:28
User entered empty.	Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:22:41

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:26:28
User entered empty.	Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:22:41

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	21 Apr 2021 19:22:41

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:26:28
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:22:52

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:26:28
User entered empty.	Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:22:52

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:26:28
User entered empty.	Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:22:52

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 19:22:52

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:26:28
User entered empty.	Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:22:52

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:26:28
User entered empty.	Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:22:52

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:26:28
User entered empty.	Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:22:52

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:26:28
User entered empty.	Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:22:52

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 19:22:52

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:26:28
User entered empty.	Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:22:52

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 19:22:52

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:22:52

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 19:22:52

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:26:28
User entered empty.	Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:22:52

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:47:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 19:22:52

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:47:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:23:09

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:47:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:26:28
User entered empty.	Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:23:09

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:47:13

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:26:28
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:23:18

US3212100

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:47:13

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	22 Apr 2021 19:26:28
User entered empty.	Afifah Ayub (b) (4) (b) (4)	21 Apr 2021 19:23:18

US3212100

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

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:17:11
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	03 Feb 2021 14:20:09

US3212100

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

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:17:11
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '02 Feb 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	03 Feb 2021 14:20:09

US3212100

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

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

[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 06:17:11
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Clinic (Clinic)'	(b) (4) Laura Ngansop Djampou (b) (4)	03 Feb 2021 14:20:09

US3212100

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

Form: Visit Date

Generated On: 09 Jun 2021 15:47:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:17:11
User entered 'UNBLND_DECIDE'	System	03 Feb 2021 14:20:09

US3212100

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

Form: Unblinding

Generated On: 09 Jun 2021 15:47:13

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:17:11
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '02 Feb 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	03 Feb 2021 14:20:27

US3212100

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

Form: Unblinding

Generated On: 09 Jun 2021 15:47:13

[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 06:17:11
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '0'	(b) (4) Afifah Ayub (b) (4)	10 Mar 2021 14:37:14
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 03:35:26

US3212100

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

Form: Unblinding

Generated On: 09 Jun 2021 15:47:13

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:17:11
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Feb 2021 14:20:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 14:20:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	03 Feb 2021 14:20:35
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 14:20:27
User entered empty.	Laura Ngansop Djampou (b) (4)	03 Feb 2021 14:20:27

US3212100

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

Form: Unblinding

Generated On: 09 Jun 2021 15:47:13

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:17:11
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Afifah Ayub (b) (4)	10 Mar 2021 14:37:14
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 03:35:26

US3212100

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

Form: Unblinding

Generated On: 09 Jun 2021 15:47:13

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:17:11
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '02 Feb 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	03 Feb 2021 14:20:27

US3212100

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

Form: Unblinding

Generated On: 09 Jun 2021 15:47:13

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:17:11
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Laura Ngansop Djampou (b) (4)	03 Feb 2021 14:20:27

US3212100

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

Form: Unblinding

Generated On: 09 Jun 2021 15:47:13

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:17:11
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Laura Ngansop Djampou (b) (4)	03 Feb 2021 14:20:27

US3212100

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

Form: Unblinding

Generated On: 09 Jun 2021 15:47:13

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:17:11
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Laura Ngansop Djampou (b) (4)	03 Feb 2021 14:20:27

US3212100

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

Form: Unblinding

Generated On: 09 Jun 2021 15:47:13

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:17:11
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'No (N)'	(b) (4) Laura Ngansop Djampou (b) (4)	03 Feb 2021 14:20:27

US3212100

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

Form: Unblinding

Generated On: 09 Jun 2021 15:47:13

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:17:11
User entered empty.	System	03 Feb 2021 14:20:27

US3212100

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

Form: Unblinding

Generated On: 09 Jun 2021 15:47:13

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:17:11
User entered empty.	System	03 Feb 2021 14:20:27

US3212100

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:47:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:17:11
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	03 Feb 2021 14:20:52

US3212100

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:47:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:17:11
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '02 Feb 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	03 Feb 2021 14:20:52

US3212100

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:17:11
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '08:46' reason for change: Data Entry Error	(b) (4)	
	Laura Ngansop Djampou	03 Feb 2021 14:21:04
	(b) (4)	
User entered '08:43'	Laura Ngansop Djampou	03 Feb 2021 14:20:52
	(b) (4)	

US3212100

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:17:11
User entered '02 Feb 2021 08:46'	System	03 Feb 2021 14:21:04
User entered '02 Feb 2021 08:43'	System	03 Feb 2021 14:20:52

US3212100

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:47:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:17:11
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	03 Feb 2021 14:21:29

US3212100

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:47:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:17:11
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '02 Feb 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	03 Feb 2021 14:21:29

US3212100

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:47:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:17:11
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '08:43'	(b) (4) Laura Ngansop Djampou (b) (4)	03 Feb 2021 14:21:29

US3212100

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:17:11
User entered '02 Feb 2021 08:43'	System	03 Feb 2021 14:21:29

US3212100

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:47:13

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:28:02
User closed query 'Per CDM : Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per Diary Dose 1 Record, symptom of Injection site pain. persist lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 08:56:32
Query 'Per CDM : Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per Diary Dose 1 Record, symptom of Injection site pain. persist lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' answered with 'added' (Site from DM).	Heather Leary (b) (4) (b) (4)	19 Apr 2021 13:44:43
User opened query 'Per CDM : Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per Diary Dose 1 Record, symptom of Injection site pain. persist lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 06:12:29
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	31 Mar 2021 00:56:54

US3212100

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:47:13

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 103, 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 08:41:18
Query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 103, 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 14:31:47
User opened query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 103, 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 14:53:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Aug 2020 15:57:24
User entered 'No (N)'	Afifah Ayub (b) (4)	10 Aug 2020 15:56:18

US3212100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43

US3212100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site bruising, LLT: Injection site bruising - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	25 Aug 2020 16:08:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 16:08:36
Data point term sent to Coder	System	25 Aug 2020 16:01:24
User entered 'Bruised injection site'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

US3212100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'No (N)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

US3212100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 10:43:48
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' answered with 'updated' (Site from DM).	Heather Leary (b) (4) (b) (4)	01 Oct 2020 20:39:39
User entered 'No (N)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	01 Oct 2020 20:39:31
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 10:19:17
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'No (N)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

US3212100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 08:17:58
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	08 Sep 2020 19:11:21
User entered '16 Aug 2020'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

US3212100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
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).	(b) (4)	31 Aug 2020 14:46:32
User entered empty; reason for change Data Entry Error	Heather Leary (b) (4)	31 Aug 2020 14:46:32
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	25 Aug 2020 16:01:03
User entered '08:00'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

US3212100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User entered empty.	System	31 Aug 2020 14:46:32
User entered '16 Aug 2020 08:00'	System	25 Aug 2020 16:01:03

US3212100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'No (N)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
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) System	25 Aug 2020 16:53:07
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	25 Aug 2020 16:53:07
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	25 Aug 2020 16:01:03
User entered '21 Aug 2020'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	31 Aug 2020 14:46:32
User entered empty; reason for change Data Entry Error	Heather Leary (b) (4)	31 Aug 2020 14:46:32
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	25 Aug 2020 16:01:03
User entered '08:00'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

US3212100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User entered empty.	System	31 Aug 2020 14:46:32
User entered '21 Aug 2020 08:00'	System	25 Aug 2020 16:01:03

US3212100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

US3212100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'No (N)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

US3212100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

US3212100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

US3212100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

US3212100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

US3212100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

US3212100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

US3212100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

US3212100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'Related (RELATED)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

US3212100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'Related (RELATED)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

US3212100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'None (NONE)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'I'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

US3212100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	(b) (4)	25 Aug 2020 16:53:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	25 Aug 2020 16:53:07
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	25 Aug 2020 16:01:03
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

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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)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty; reason for change Data Entry Error	(b) (4) Afifah Ayub (b) (4)	25 Aug 2020 16:53:07
User entered 'NA'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:01:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User entered '0'	System	25 Aug 2020 16:01:03

US3212100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43
User entered '0'	System	25 Aug 2020 16:01:03

US3212100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:47:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:43

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Bone related signs and symptoms, PT: Pain in jaw, LLT: Jaw pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	25 Aug 2020 16:07:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 16:07:32
Data point term sent to Coder	System	25 Aug 2020 16:06:37
User entered 'jaw pain'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'No (N)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	25 Aug 2020 16:08:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Aug 2020 16:08:26
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:08:26
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 16:05:37
User entered empty.	Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	25 Aug 2020 16:07:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Aug 2020 16:07:55
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:07:55
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 16:05:37
User entered empty.	Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 08:18:07
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	08 Sep 2020 19:11:21
User entered '14 Aug 2020'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
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	31 Aug 2020 14:46:52
User entered empty; reason for change Data Entry Error	Heather Leary (b) (4)	31 Aug 2020 14:46:52
	(b) (4)	
User entered '08:00' reason for change: Data Entry Error	Laura Ngansop Djampou	25 Aug 2020 16:13:17
	(b) (4)	
User entered '8:00' reason for change: Data Entry Error	Laura Ngansop Djampou	25 Aug 2020 16:08:26
	(b) (4)	
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	25 Aug 2020 16:05:37
User entered '08:00'	Laura Ngansop Djampou	25 Aug 2020 16:05:37
	(b) (4)	

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User entered empty.	System	31 Aug 2020 14:46:52
User entered '14 Aug 2020 08:00'	System	25 Aug 2020 16:13:17
User entered '14 Aug 2020 8:00'	System	25 Aug 2020 16:08:26
User entered '14 Aug 2020 08:00'	System	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:04:55
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'updated' (Site from DM).	Anna Pena (b) (4) (b) (4)	25 Nov 2020 15:14:13
User entered 'No (N)' reason for change: Data Entry Error	Anna Pena (b) (4) (b) (4)	25 Nov 2020 15:13:53
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 06:57:08
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
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) System	25 Nov 2020 15:14:02
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	25 Nov 2020 15:14:02
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	25 Nov 2020 15:13:53
User entered '29 Aug 2020' reason for change: Data Entry Error	Anna Pena (b) (4) (b) (4)	25 Nov 2020 15:13:53
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	25 Aug 2020 16:59:11
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	25 Aug 2020 16:59:11
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	25 Aug 2020 16:13:17
User entered empty.	Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User entered empty.	System	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'No (N)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'Not Related (NOT RELATED)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:40:56
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.	Anna Pena (b) (4) (b) (4)	18 Nov 2020 15:48:49
' answered with 'updated' (Site from DM).		
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Anna Pena (b) (4) (b) (4)	18 Nov 2020 15:48:42
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	Deepika Srirama (3829 - Deepika@941)	18 Nov 2020 09:12:58
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 16:13:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Aug 2020 16:13:17
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:13:17
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 16:05:37
User entered empty.	Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'None (NONE)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'I'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Anna Pena (b) (4)	25 Nov 2020 15:14:02
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	25 Aug 2020 16:59:39
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	25 Aug 2020 16:59:11
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	25 Aug 2020 16:59:11
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	25 Aug 2020 16:13:17
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:13:17
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	25 Aug 2020 16:05:37
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty; reason for change Data Entry Error	(b) (4) Afifah Ayub (b) (4)	25 Aug 2020 16:59:39
User entered 'Plans to see dentist'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User entered '0'	System	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45
User entered '0'	System	25 Aug 2020 16:05:37

US3212100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:47:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:45

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	25 Aug 2020 16:19:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 16:19:31
Data point term sent to Coder	System	25 Aug 2020 16:18:16
User entered 'LOWER BACK PAIN'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'No (N)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'No (N)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'No (N)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 08:18:20
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	08 Sep 2020 19:11:21
User entered '14 Aug 2020'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
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).	(b) (4)	31 Aug 2020 14:47:04
User entered empty; reason for change Data Entry Error	Heather Leary (b) (4)	31 Aug 2020 14:47:04
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	25 Aug 2020 16:18:05
User entered '10:00'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User entered empty.	System	31 Aug 2020 14:47:04
User entered '14 Aug 2020 10:00'	System	25 Aug 2020 16:18:05

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:05:42
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' answered with 'updated' (Site from DM).	Anna Pena (b) (4) (b) (4)	25 Nov 2020 15:15:25
User entered 'No (N)' reason for change: Data Entry Error	Anna Pena (b) (4) (b) (4)	25 Nov 2020 15:15:19
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 06:57:19
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '01 Sep 2020' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Anna Pena (b) (4)	25 Nov 2020 15:15:19
	(b) (4)	
	Laura Ngansop Djampou	25 Aug 2020 16:18:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User entered empty.	System	25 Aug 2020 16:18:05

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'No (N)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'Not Related (NOT RELATED)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:41:44
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.	Anna Pena (b) (4) (b) (4)	18 Nov 2020 15:49:19
' answered with 'updated' (Site from DM).		
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Anna Pena (b) (4) (b) (4)	18 Nov 2020 15:49:12
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:13:14
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 16:58:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Aug 2020 16:58:23
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	25 Aug 2020 16:58:23
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 16:18:05
User entered empty.	Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'None (NONE)'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'I'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Anna Pena (b) (4) (b) (4)	25 Nov 2020 15:15:19
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	25 Aug 2020 16:58:23
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	25 Aug 2020 16:18:05
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty; reason for change Data Entry Error	(b) (4) Afifah Ayub (b) (4)	25 Aug 2020 16:58:23
User entered 'na'	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty.	(b) (4) Laura Ngansop Djampou (b) (4)	25 Aug 2020 16:18:05

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User entered '0'	System	25 Aug 2020 16:18:05

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48
User entered '0'	System	25 Aug 2020 16:18:05

US3212100

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:47:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:48

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User closed query 'Per DM CLR: Please review AE and please update to specify whether Rash is Urticarial or Non-urticarial. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:42:00
Query 'Per DM CLR: Please review AE and please update to specify whether Rash is Urticarial or Non-urticarial. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'unknown ' (Site from DM).	Reagan Reed (b) (4) (b) (4)	21 Jan 2021 15:43:30
User opened query 'Per DM CLR: Please review AE and please update to specify whether Rash is Urticarial or Non-urticarial. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 20:32:10
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Rash trunk - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 15:21:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 15:21:15
Data point term sent to Coder	System	25 Nov 2020 14:40:21
User entered 'skin rash of right breast'	Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'Yes (Y)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '16 Nov 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User entered empty.	System	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '20 Nov 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User entered empty.	System	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'Not Related (NOT RELATED)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'Not Related (NOT RELATED)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'None (NONE)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'I'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User entered '0'	System	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54
User entered 'I'	System	25 Nov 2020 14:39:49

US3212100

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:47:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:00:54

US3212100

Folder: Adverse Events

Form: Adverse Events (6)

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[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 17:12:00
User entered 'USA-US115-2021-mRNA-1273-P301000001'	System	04 Jan 2021 17:11:55
User entered 'New'	(b) (4), (b) (6)	04 Jan 2021 17:11:55

US3212100

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Reproductive tract disorders NEC, HLT: Reproductive tract signs and symptoms NEC, PT: Pelvic pain, LLT: Pelvic pain - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 14:01:29
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 14:01:29
	(b) (4)	
Data point term sent to Coder	System	25 Mar 2021 14:00:56
Coding entries removed.	Jagruti Patel (b) (4)	25 Mar 2021 14:00:17
	(b) (4)	
User entered 'Pelvic Pain' reason for change: Data Entry Error	Jagruti Patel (b) (4)	25 Mar 2021 14:00:17
	(b) (4)	
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Fibroids - version MedDRA\\23.0.	Coder Import (b) (4)	03 Jan 2021 13:04:28
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Jan 2021 13:04:28
	(b) (4)	
Data point term sent to Coder	System	30 Dec 2020 22:45:43
User entered 'Extensive fibroids complicating planned Hysterectomy'	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
User entered 'Yes (Y)'	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

US3212100

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
User entered 'No (N)'	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
User entered 'No (N)'	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

US3212100

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
User entered '15 Dec 2020'	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

US3212100

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
User entered empty.	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Dec 2020 22:44:47

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
User entered 'No (N)'	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
User entered '27 Dec 2020' reason for change: Data Entry Error	Jagruti Patel (b) (4)	25 Mar 2021 20:48:05
User entered '19 Dec 2020' reason for change: Data Entry Error	Jagruti Patel (b) (4)	25 Mar 2021 14:00:17
User closed query 'PV Query: As the fibroids prolonged hospitalization, please consider updating end date for the event to when the event resolved.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 13:59:10
Query 'PV Query: As the fibroids prolonged hospitalization, please consider updating end date for the event to when the event resolved.' answered with 'Hysterectomy also happened on 15Dec2020 - response is correct as entered' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 21:05:57
User opened query 'PV Query: As the fibroids prolonged hospitalization, please consider updating end date for the event to when the event resolved.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 19:46:45
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	02 Feb 2021 16:32:19
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	02 Feb 2021 16:32:19
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	30 Dec 2020 22:44:47
User entered '15 Dec 2020'	Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:44:47

US3212100

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
User entered empty.	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

US3212100

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: As the fibroids prolonged hospitalization, please consider updating end date for the event to when the event resolved.' canceled (Site from Safety).	Victoria Brundage (4240 - vickibrundage1)	09 Feb 2021 19:46:29
User opened query 'PV Query: As the fibroids prolonged hospitalization, please consider updating end date for the event to when the event resolved.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 18:37:58
User entered empty.	System	30 Dec 2020 22:44:47

US3212100

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
Query 'PV Query: Since the subject was hospitalized for the event of extensive fibroids complicating planned hysterectomy, appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 18:53:47
User opened query 'PV Query: Since the subject was hospitalized for the event of extensive fibroids complicating planned hysterectomy, appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 14:52:44
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

US3212100

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
User entered 'Yes (Y)'	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

US3212100

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
User entered '0'	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

US3212100

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
User entered '0'	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

US3212100

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
User entered '1'	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
User entered '15 Dec 2020'	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

US3212100

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 13:43:14
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'sent' (Site from Safety).	Jagruti Patel (b) (4)	25 Mar 2021 20:48:12
User entered '17 Dec 2020' reason for change: Data Entry Error	(b) (4)	25 Mar 2021 20:48:05
User entered '27 Dec 2020' reason for change: Data Entry Error	Jagruti Patel (b) (4)	25 Mar 2021 20:47:35
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 14:53:15
User entered '17 Dec 2020'	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

US3212100

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
User entered 'No (N)'	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

US3212100

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
User entered empty.	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

US3212100

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
User entered '0'	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

US3212100

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
User entered '0'	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

US3212100

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
User entered '0'	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
User entered '0'	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:15:40
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Ibuprofen and Codine already listed are related to this AE. ' (Site from DM).	Jagruti Patel (b) (4)	22 Mar 2021 17:06:11
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	24 Jan 2021 07:29:15
User entered 'I'	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Response noted however, there is no MH for 'PELVIC PAIN'? Please review and add an entry and applicable details to the Medical History eCRF as appropriate or, provide record number this indication pertains to. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 16:26:44
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
Query 'Per CDM: Response noted however, there is no MH for 'PELVIC PAIN'? Please review and add an entry and applicable details to the Medical History eCRF as appropriate or, provide record number this indication pertains to. Thank you.' answered with 'leiomyoma of uterus ' (Site from DM).	(b) (4) Reagan Reed (b) (4)	29 Mar 2021 13:15:49
User opened query 'Per CDM: Response noted however, there is no MH for 'PELVIC PAIN'? Please review and add an entry and applicable details to the Medical History eCRF as appropriate or, provide record number this indication pertains to. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 09:44:15
User closed query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is MEDICAL HISTORY and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 09:44:15
Query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is MEDICAL HISTORY and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' answered with 'indication is both - medical history and AE. Updated indication for con proc.' (Site from DM).	Jagruti Patel (b) (4)	25 Mar 2021 14:06:01
User opened query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is MEDICAL HISTORY and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Jan 2021 07:29:05

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered 'I'	Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:44:47

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Folder: Adverse Events

Form: Adverse Events (6)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 16:42:29
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated' (Site from Safety).	Reagan Reed (b) (4)	02 Feb 2021 16:32:44
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Reagan Reed (b) (4)	02 Feb 2021 16:32:19
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 14:52:54
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

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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)	31 Mar 2021 00:56:54
	(b) (4)	
User entered empty.	Reagan Reed (b) (4)	30 Dec 2020 22:44:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	31 Mar 2021 00:56:54
	(b) (4)	
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)	26 Mar 2021 13:42:48
User closed query 'PV -Query. Kindly request for the subjects' obstetric and gynecological history' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 13:42:45
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 13:42:43
Query 'PV -Query. Kindly request for the subjects' obstetric and gynecological history' answered with 'records sent' (Site from Safety).	Jagruti Patel (b) (4) (b) (4)	25 Mar 2021 20:48:43
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'sent' (Site from Safety).	Jagruti Patel (b) (4) (b) (4)	25 Mar 2021 20:48:38
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 'records sent' (Site from Safety).	Jagruti Patel (b) (4) (b) (4)	25 Mar 2021 20:48:33
User opened query 'PV -Query. Kindly request for the subjects' obstetric and gynecological history' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 14:53:26

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Folder: Adverse Events

Form: Adverse Events (6)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 14:53:02
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)	08 Jan 2021 14:52:12
User entered 'She had a planned hysterectomy to remove fibroids. During the surgery, the fibroids were extensive, so the fallopian tubes were not removed. She remained hospitalized for 2 days. The complication of extensive fibroids may have prolonged the planned hospitalization.'	Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:44:47

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Folder: Adverse Events

Form: Adverse Events (6)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Dec 2020 22:44:47

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Folder: Adverse Events

Form: Adverse Events (6)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Dec 2020 22:44:47

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:47:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Dec 2020 22:44:47

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:47:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	25 Mar 2021 13:27:53

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:47:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Injection site pain - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 13:45:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 13:45:40
Data point term sent to Coder	System	19 Apr 2021 13:45:02
User entered 'injection site pain'	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:47:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User entered 'No (N)'	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:47:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User entered 'Yes (Y)'	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

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Folder: Adverse Events

Form: Adverse Events (7)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User entered 'No (N)'	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User entered '10 Aug 2020'	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:47:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Apr 2021 14:31:54
User entered '15:41' reason for change: Data Entry Error	System	19 Apr 2021 14:31:54
User opened query 'Data is required. Please provide.' (Site from System).	Heather Leary (b) (4)	19 Apr 2021 14:31:54
User entered empty.	(b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	System	19 Apr 2021 13:44:37
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	19 Apr 2021 13:44:37
	(b) (4)	19 Apr 2021 13:44:37
	Laura Ngansop Djampou	25 Mar 2021 13:50:59
	(b) (4)	25 Mar 2021 13:50:59
	Reagan Reed (b) (4)	25 Mar 2021 13:27:53
	(b) (4)	25 Mar 2021 13:27:53

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Folder: Adverse Events

Form: Adverse Events (7)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User entered '10 Aug 2020 15:41'	System	19 Apr 2021 14:31:54
User entered empty.	System	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

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Folder: Adverse Events

Form: Adverse Events (7)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User entered 'No (N)'	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User entered '20 Aug 2020'	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

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Folder: Adverse Events

Form: Adverse Events (7)

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Apr 2021 14:31:54
User entered '12:11' reason for change: Data Entry Error	System	19 Apr 2021 14:31:54
User opened query 'Data is required. Please provide.' (Site from System).	Heather Leary (b) (4)	19 Apr 2021 14:31:54
User entered empty.	(b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	System	19 Apr 2021 13:44:37
DataPoint inactivated with code reason code Data not required.	Heather Leary (b) (4)	19 Apr 2021 13:44:37
	(b) (4)	19 Apr 2021 13:44:37
	Laura Ngansop Djampou	25 Mar 2021 13:50:59
	(b) (4)	25 Mar 2021 13:50:59
	Reagan Reed (b) (4)	25 Mar 2021 13:27:53
	(b) (4)	25 Mar 2021 13:27:53

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Folder: Adverse Events

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User entered '20 Aug 2020 12:11'	System	19 Apr 2021 14:31:54
User entered empty.	System	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:47:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 18:54:24
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Heather Leary (b) (4)	19 Apr 2021 18:54:24
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Laura Ngansop Djampou	25 Mar 2021 13:50:59
	(b) (4)	
	Reagan Reed (b) (4)	25 Mar 2021 13:27:53
	(b) (4)	

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User entered 'No (N)'	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:47:13

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User entered '0'	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

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Folder: Adverse Events

Form: Adverse Events (7)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User entered '0'	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

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Folder: Adverse Events

Form: Adverse Events (7)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User entered '0'	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

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Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User entered empty.	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User entered empty.	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

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Folder: Adverse Events

Form: Adverse Events (7)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User entered empty.	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

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Folder: Adverse Events

Form: Adverse Events (7)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User entered empty.	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

US3212100

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:47:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User entered '0'	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

US3212100

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:47:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User entered '0'	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:47:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User entered '0'	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:47:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Apr 2021 18:54:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 18:54:24
User entered 'Related (RELATED)' reason for change: Data Entry Error	Heather Leary (b) (4)	19 Apr 2021 18:54:24
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Apr 2021 13:44:37
User entered empty.	System	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint inactivated with code reason code Data not required.	(b) (4)	25 Mar 2021 13:50:59
	Laura Ngansop Djampou	25 Mar 2021 13:27:53
	(b) (4)	
	Reagan Reed	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:47:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 18:54:24
User entered 'Related (RELATED)' reason for change: Data Entry Error	Heather Leary (b) (4)	19 Apr 2021 18:54:24
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Laura Ngansop Djampou	25 Mar 2021 13:50:59
	(b) (4)	
	Reagan Reed (b) (4)	25 Mar 2021 13:27:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:47:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User entered 'None (NONE)'	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:47:13

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User entered 'I'	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

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Folder: Adverse Events

Form: Adverse Events (7)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User entered '0'	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

US3212100

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:47:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User entered '0'	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

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Folder: Adverse Events

Form: Adverse Events (7)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:47:13

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User entered empty.	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

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Folder: Adverse Events

Form: Adverse Events (7)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:37:35
User entered empty.	Heather Leary (b) (4)	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

US3212100

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:47:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User entered '0'	System	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53

US3212100

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:47:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
User entered '0'	System	19 Apr 2021 13:44:37
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou	25 Mar 2021 13:50:59
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4)	25 Mar 2021 13:27:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:47:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:01:02
DataPoint activated with code reason code Data required.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:50:59
DataPoint inactivated with code reason code Data not required.	Reagan Reed (b) (4) (b) (4)	25 Mar 2021 13:27:53

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:28:02
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User closed query 'Per DM CLR Requery: Response to previous query noted. However, start/stop dates (16Aug2020) of CM# 6 Ibuprofen doesn't match the diary dates for Pain at Injection Site (Dose 2 Day 2) and Headache (Dose 2 Day 2-4). Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 12:06:57
Query 'Per DM CLR Requery: Response to previous query noted. However, start/stop dates (16Aug2020) of CM# 6 Ibuprofen doesn't match the diary dates for Pain at Injection Site (Dose 2 Day 2) and Headache (Dose 2 Day 2-4). Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'Per source prescription medication not used, subject regularly takes IBUPROFEN for medical history item SINUS PRESSURE/PAIN; updated conmed indication to include fever or pain reactivity.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 21:08:22
User opened query 'Per DM CLR Requery: Response to previous query noted. However, start/stop dates (16Aug2020) of CM# 6 Ibuprofen doesn't match the diary dates for Pain at Injection Site (Dose 2 Day 2) and Headache (Dose 2 Day 2-4). Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 14:09:14
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site and Diary Dose 2 Day 2, 3 and 4 Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 14:09:55

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site and Diary Dose 2 Day 2, 3 and 4 Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'Per source prescription medication not used, subject regularly takes IBUPROFEN for medical history item SINUS PRESSURE/PAIN; updated conmed indication to include fever or pain reactogenicity.' (Site from DM).	Heather Leary (b) (4) (b) (4)	25 Jan 2021 21:20:18
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site and Diary Dose 2 Day 2, 3 and 4 Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4)	25 Jan 2021 04:15:06
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:51:45

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:47:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	11 Aug 2020 13:32:14
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 Aug 2020 13:32:14
Data point term sent to Coder	System	10 Aug 2020 15:53:32
User entered 'Metformin'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:52:34

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:47:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:52:34

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:47:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
	(b) (4)	
User entered 'glucose intolerance'	Afifah Ayub (b) (4)	10 Aug 2020 15:52:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:47:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered '500'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:52:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:47:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered 'mg (mg)'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:52:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:47:13

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered empty.	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:52:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:47:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'once daily (QD)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:52:34

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:47:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered empty.	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:52:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:47:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
	(b) (4)	
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4)	10 Aug 2020 15:52:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:47:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered empty.	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:52:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:47:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
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)	
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.'	(b) (4), (b) (6)	11 Aug 2020 03:12:34
answered with 'Subject is currently on the medication' (Site from System).		
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.'	Afifah Ayub (b) (4)	10 Aug 2020 17:57:11
answered with 'Subject is currently on the medication' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 16:31:34
User entered 'UN UNK 2007'	Afifah Ayub (b) (4)	10 Aug 2020 15:52:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:47:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered '0'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:52:34

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:47:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:52:34

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:47:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered empty.	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:52:34

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:47:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:52:34

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:47:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 15:52:34

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:47:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 15:52:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:47:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 15:52:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:47:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
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.	(b) (4) Coder Import (b) (4)	28 Sep 2020 11:39:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 11:39:33
Data point term sent to Coder	System	25 Sep 2020 16:49:22
Coding entries removed.	Afifah Ayub (b) (4)	25 Sep 2020 16:49:06
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.	(b) (4) Coder Import (b) (4)	17 Aug 2020 07:30:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 07:30:18
Data point term sent to Coder	System	10 Aug 2020 15:53:34
User entered 'mulivitamin'	Afifah Ayub (b) (4)	10 Aug 2020 15:53:20

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:47:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 11:11:24
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM).	Reagan Reed (b) (4) (b) (4)	24 Feb 2021 14:08:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	24 Feb 2021 14:08:43
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 09:24:29
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:53:20

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:47:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Wellness' reason for change: New Information	(b) (4) Afifah Ayub (b) (4)	25 Sep 2020 16:49:06
User entered 'vitamins'	(b) (4) Afifah Ayub (b) (4)	10 Aug 2020 15:53:20

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:47:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User closed query 'Per DM CLR: Please provide the actual dose for this medications there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. Otherwise, provide tablet count if available (example: Dose=1 unit=tablet). Update as appropriate or provide clarification ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 12:08:57
User closed query 'Per CDM: As per CCG Page no: 36, Please review and update the text field accordingly. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 11:30:13
Query 'Per DM CLR: Please provide the actual dose for this medications there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. Otherwise, provide tablet count if available (example: Dose=1 unit=tablet). Update as appropriate or provide clarification ' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4) (b) (4)	25 Sep 2020 16:49:37
Query 'Per CDM: As per CCG Page no: 36, Please review and update the text field accordingly. ' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4) (b) (4)	25 Sep 2020 16:49:30
User entered '1' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	25 Sep 2020 16:49:06
User opened query 'Per DM CLR: Please provide the actual dose for this medications there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. Otherwise, provide tablet count if available (example: Dose=1 unit=tablet). Update as appropriate or provide clarification ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 09:20:50
User opened query 'Per CDM: As per CCG Page no: 36, Please review and update the text field accordingly. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:24:36
User entered 'OTC'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:53:20

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:47:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'tablet (TABLET)' reason for change:	(b) (4)	
Data Entry Error	Afifah Ayub (b) (4)	25 Sep 2020 16:49:06
User entered 'mg (mg)'	(b) (4)	
	Afifah Ayub (b) (4)	10 Aug 2020 15:53:20
	(b) (4)	

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:47:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered empty.	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:53:20

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:47:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
	(b) (4)	
User entered 'once daily (QD)'	Afifah Ayub (b) (4)	10 Aug 2020 15:53:20
	(b) (4)	

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:47:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered empty.	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:53:20

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:47:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:53:20

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:47:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered empty.	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:53:20

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:47:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
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)	
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.'	(b) (4), (b) (6)	11 Aug 2020 03:12:39
answered with 'Subject is currently on the medication.' (Site from System).		
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).	Afifah Ayub (b) (4)	10 Aug 2020 17:57:40
User entered 'UN UNK 2005'	(b) (4)	
	System	10 Aug 2020 16:31:34
	Afifah Ayub (b) (4)	10 Aug 2020 15:53:20
	(b) (4)	

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:47:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered '0'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:53:20

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:47:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:53:20

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:47:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered empty.	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:53:20

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:47:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:53:20

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:47:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 15:53:20

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:47:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 15:53:20

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:47:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 15:53:20

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:47:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Aug 2020 11:25:11
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 Aug 2020 11:25:11
Data point term sent to Coder	System	10 Aug 2020 15:54:35
User entered 'vitamin C'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:53:56

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:47:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 11:11:38
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM).	Reagan Reed (b) (4) (b) (4)	24 Feb 2021 14:09:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	24 Feb 2021 14:09:15
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 09:24:37
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:53:56

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:47:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'PREVENTATIVE'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:53:56

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:47:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User closed query 'Per DM CLR: Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 11:56:15
User closed query 'Per CDM: As per CCG Page no: 36, Please review and update the text field accordingly. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 11:30:37
Query 'Per DM CLR: Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'updated' (Site from DM).	Anna Pena (b) (4) (b) (4)	25 Sep 2020 21:21:00
Query 'Per CDM: As per CCG Page no: 36, Please review and update the text field accordingly. ' answered with 'updated' (Site from DM).	Anna Pena (b) (4) (b) (4)	25 Sep 2020 21:20:54
User entered '1000' reason for change: Data Entry Error	Anna Pena (b) (4) (b) (4)	25 Sep 2020 21:20:43
User opened query 'Per DM CLR: Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 09:21:12
User opened query 'Per CDM: As per CCG Page no: 36, Please review and update the text field accordingly. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:24:46
User entered 'OTC'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:53:56

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:47:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered 'mg (mg)'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:53:56

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:47:13

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered empty.	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:53:56

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:47:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'once daily (QD)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:53:56

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:47:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered empty.	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:53:56

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:47:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:53:56

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:47:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered empty.	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:53:56

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:47:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
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)	
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.'	(b) (4), (b) (6)	11 Aug 2020 03:12:44
answered with 'Subject is currently on the medication' (Site from System).		
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.'	Afifah Ayub (b) (4)	10 Aug 2020 17:57:50
answered with 'Subject is currently on the medication' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 16:31:34
User entered 'UN UNK 2019'	Afifah Ayub (b) (4)	10 Aug 2020 15:53:56
	(b) (4)	

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:47:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered '0'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:53:56

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:47:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:53:56

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:47:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered empty.	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:53:56

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:47:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:53:56

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:47:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 15:53:56

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:47:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 15:53:56

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:47:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 15:53:56

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:47:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: AMINO ACIDS, INCL. COMBINATIONS WITH POLYPEPTIDES, PRODUCT: ISOLEUCINE;LEUCINE;VALINE, PRODUCTSYNONYM: NOW BRANCHED CHAIN AMINO ACIDS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Aug 2020 10:47:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 10:47:32
Data point term sent to Coder	System	10 Aug 2020 15:55:36
User entered 'BCAA Branched-chain amino acid'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:54:44

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:47:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 11:11:45
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM).	Reagan Reed (b) (4) (b) (4)	24 Feb 2021 14:09:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	24 Feb 2021 14:09:31
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 09:24:56
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:54:44

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:47:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'muscle building'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:54:44

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:47:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 12:01:19
User closed query 'Per CDM: As per CCG Page no: 36, Please review and update the text field accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 12:00:56
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated' (Site from DM).	Anna Pena (b) (4)	13 Oct 2020 20:59:43
Query 'Per CDM: As per CCG Page no: 36, Please review and update the text field accordingly. ' answered with 'updated' (Site from DM).	Anna Pena (b) (4)	13 Oct 2020 20:59:37
User entered 'unk' reason for change: Data Entry Error	Anna Pena (b) (4)	13 Oct 2020 20:58:15
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 09:20:02
User opened query 'Per CDM: As per CCG Page no: 36, Please review and update the text field accordingly. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:25:17
User entered 'OTC'	Afifah Ayub (b) (4)	10 Aug 2020 15:54:44

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:47:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered 'mg (mg)'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:54:44

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:47:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered empty.	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:54:44

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:47:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
	(b) (4)	
User entered 'three times daily (TID)'	Afifah Ayub (b) (4)	10 Aug 2020 15:54:44
	(b) (4)	

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:47:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered empty.	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:54:44

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:47:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:54:44

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:47:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered empty.	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:54:44

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:47:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
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)	
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.'	(b) (4), (b) (6)	11 Aug 2020 03:12:50
answered with 'Subject is currently on the medication' (Site from System).		
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.'	Afifah Ayub (b) (4)	10 Aug 2020 17:57:59
answered with 'Subject is currently on the medication' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 16:31:34
User entered 'UN UNK 2017'	Afifah Ayub (b) (4)	10 Aug 2020 15:54:44
	(b) (4)	

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:47:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered '0'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:54:44

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:47:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:54:44

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:47:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered empty.	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:54:44

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:47:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:54:44

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:47:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Aug 2020 15:54:44

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:47:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 15:54:44

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:47:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 15:54:44

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:47:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:17
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE, PRODUCTSYNONYM: LO LOESTRIN FE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 07:39:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 07:39:26
Data point term sent to Coder	System	10 Aug 2020 15:56:37
User entered 'Lo Loestrin'	Afifah Ayub (b) (4)	10 Aug 2020 15:55:51

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:47:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:17
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 11:11:52
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM).	Reagan Reed (b) (4) (b) (4)	24 Feb 2021 14:10:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	24 Feb 2021 14:09:56
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 09:25:10
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:55:51

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:47:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:17
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'birth control'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:55:51

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:47:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:17
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User closed query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only (dose = 1/10/10). Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:05:43
Query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only (dose = 1/10/10). Update as appropriate. ' answered with 'corrected' (Site from DM).	Reagan Reed (b) (4) (b) (4)	12 Mar 2021 15:05:21
User entered '1 /10 /10' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	12 Mar 2021 15:05:15
User opened query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only (dose = 1/10/10). Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 06:50:14
User entered '1 mg/10 mcg/10 mcg'	Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:55:51

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:47:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:17
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Other (OTHER)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:55:51

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:47:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:17
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'MG/MCG/MCG' reason for change:	(b) (4)	
Data Entry Error	Reagan Reed (b) (4)	12 Mar 2021 15:05:15
User entered '1 mg/10 mcg/10 mcg'	(b) (4)	
	Afifah Ayub (b) (4)	10 Aug 2020 15:55:51
	(b) (4)	

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:47:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:17
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'once daily (QD)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:55:51

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:47:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:17
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:55:51

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:47:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:17
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Oral (ORAL)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:55:51

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:47:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:17
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:55:51

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:47:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:17
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
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)	
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.'	(b) (4), (b) (6)	11 Aug 2020 03:12:55
answered with 'Subject is currently on the medication' (Site from System).		
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).	Afifah Ayub (b) (4)	10 Aug 2020 17:58:09
User entered '01 Mar 2020'	(b) (4)	
	System	10 Aug 2020 16:31:34
	Afifah Ayub (b) (4)	10 Aug 2020 15:55:51
	(b) (4)	

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:47:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:17
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:55:51

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:47:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:17
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	11 Mar 2021 14:29:08
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	10 Aug 2020 15:55:51

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:47:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:17
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '10 Dec 2020' reason for change: Data Entry Error	(b) (4)	11 Mar 2021 14:29:08
User entered empty.	Laura Ngansop Djampou (b) (4)	10 Aug 2020 15:55:51
	Afifah Ayub (b) (4)	
	(b) (4)	

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:47:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:17
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	10 Aug 2020 15:55:51

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:47:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:17
User entered '1'	System	10 Aug 2020 15:55:51

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:47:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:17
User entered '1'	System	10 Aug 2020 15:55:51

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:47:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:17
User entered '804 (804)'	System	10 Aug 2020 15:55:51

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:47:13

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
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 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Apr 2021 14:03:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 14:03:28
Data point term sent to Coder Coding entries removed.	System Reagan Reed (b) (4) (b) (4)	31 Mar 2021 14:27:24 31 Mar 2021 14:26:33
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 08:04:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 08:04:06
Data point term sent to Coder Coding entries removed.	System Heather Leary (b) (4) (b) (4)	25 Jan 2021 21:19:42 25 Jan 2021 21:19:17
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:45:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:45:26
Data point term sent to Coder	System	05 Oct 2020 16:11:08

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:47:13

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	Afifah Ayub (b) (4)	05 Oct 2020 16:10:43
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 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Aug 2020 21:40:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 21:40:18
Data point term sent to Coder	System	17 Aug 2020 21:39:33
User entered 'Ibuprofen'	Heather Leary (b) (4) (b) (4)	17 Aug 2020 21:38:47

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:47:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	17 Aug 2020 21:38:47

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:47:13

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: 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)	05 Apr 2021 09:39:45
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Query 'Per DM CLR: 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 'updated' (Site from DM).	Reagan Reed (b) (4)	31 Mar 2021 14:26:45
User entered 'SEASONAL ALLERGIC RHINITIS, FEVER/PAIN REACTOGENICITY' reason for change: Data Entry Error	Reagan Reed (b) (4)	31 Mar 2021 14:26:33
User opened query 'Per DM CLR: 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)	29 Mar 2021 02:54:58
User closed query 'Per DM CLR: Please specify the actual symptoms recorded in the diary (e.g. INJECTION SITE PAIN, HEADACHE etc.). Update and reconcile with AE eCRF if it fits the protocol specified criteria for AE reporting. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	20 Mar 2021 16:23:29
Query 'Per DM CLR: Please specify the actual symptoms recorded in the diary (e.g. INJECTION SITE PAIN, HEADACHE etc.). Update and reconcile with AE eCRF if it fits the protocol specified criteria for AE reporting. Otherwise, clarify. ' answered with 'not required per protocol ' (Site from DM).	Reagan Reed (b) (4)	18 Mar 2021 15:32:04
User opened query 'Per DM CLR: Please specify the actual symptoms recorded in the diary (e.g. INJECTION SITE PAIN, HEADACHE etc.). Update and reconcile with AE eCRF if it fits the protocol specified criteria for AE reporting. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 11:16:36
User entered 'SINUS PRESSURE/PAIN, fever/pain reactogenicity' reason for change: Data Entry Error	Heather Leary (b) (4)	25 Jan 2021 21:19:17

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:47:13

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the 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 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 HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 11:14:33
User entered 'sinus pressure/pain' reason for change: Afifah Ayub Data Entry Error	(b) (4)	05 Oct 2020 16:10:43
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the 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 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 HEADACHE did not meet the AE reporting criteria. ' answered with 'solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	Afifah Ayub (b) (4)	28 Sep 2020 18:25:08

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:47:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '200-400' reason for change: Data Entry Error	(b) (4)	
	Laura Ngansop Djampou	11 Mar 2021 14:32:46
	(b) (4)	
User entered '400'	Heather Leary (b) (4)	17 Aug 2020 21:38:47
	(b) (4)	

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:47:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
	(b) (4)	
User entered 'mg (mg)'	Heather Leary (b) (4)	17 Aug 2020 21:38:47
	(b) (4)	

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:47:13

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered empty.	Heather Leary (b) (4) (b) (4)	17 Aug 2020 21:38:47

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:47:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'as needed (PRN)' reason for change:	(b) (4)	
Data Entry Error	Laura Ngansop Djampou (b) (4)	11 Mar 2021 14:32:46
User entered 'once (ONCE)'	Heather Leary (b) (4)	17 Aug 2020 21:38:47
	(b) (4)	

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:47:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered empty.	Heather Leary (b) (4) (b) (4)	17 Aug 2020 21:38:47

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:47:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Oral (ORAL)'	(b) (4) Heather Leary (b) (4)	17 Aug 2020 21:38:47
	(b) (4)	

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:47:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered empty.	Heather Leary (b) (4) (b) (4)	17 Aug 2020 21:38:47

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'UN UNK 2000' reason for change: Data Entry Error	(b) (4) Laura Ngansop Djampou (b) (4)	11 Mar 2021 14:32:05
User entered '16 Aug 2020'	Heather Leary (b) (4) (b) (4)	17 Aug 2020 21:38:47

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:47:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered '0'	Heather Leary (b) (4) (b) (4)	17 Aug 2020 21:38:47

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:47:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Laura Ngansop Djampou	11 Mar 2021 14:32:05
User entered 'No (N)'	(b) (4) Heather Leary (b) (4)	17 Aug 2020 21:38:47
	(b) (4)	

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:47:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered empty; reason for change Data Entry Error	(b) (4)	
	Laura Ngansop Djampou	11 Mar 2021 14:32:05
	(b) (4)	
User entered '16 Aug 2020'	Heather Leary (b) (4)	17 Aug 2020 21:38:47
	(b) (4)	

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:47:13

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Mar 2021 16:23:50
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	Reagan Reed (b) (4) (b) (4)	18 Mar 2021 15:32:42
User entered 'No (N)' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	18 Mar 2021 15:32:17
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 11:16:46
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	17 Aug 2020 21:38:47

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:47:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 21:38:47

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:47:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 21:38:47

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:47:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 21:38:47

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:47:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:22
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Nov 2020 06:42:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 06:42:11
Data point term sent to Coder	System	23 Nov 2020 15:55:50
User entered 'Clindamycin'	Afifah Ayub (b) (4)	23 Nov 2020 15:55:15

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:47:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:22
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Nov 2020 15:55:15

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:47:13

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:22
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User closed query 'Per DM CLR: Please review Indication and specify the location of Rash and indicate whether this is Urticarial or Non-urticarial rash. Please update and ensure that there is a corresponding MH record to match the indication. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:12:46
Query 'Per DM CLR: Please review Indication and specify the location of Rash and indicate whether this is Urticarial or Non-urticarial rash. Please update and ensure that there is a corresponding MH record to match the indication. Otherwise, clarify.' answered with 'unknown etiology ' (Site from DM).	Reagan Reed (b) (4) (b) (4)	19 Jan 2021 22:43:52
User opened query 'Per DM CLR: Please review Indication and specify the location of Rash and indicate whether this is Urticarial or Non-urticarial rash. Please update and ensure that there is a corresponding MH record to match the indication. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Jan 2021 02:06:59
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 as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 18:56:11
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 as appropriate. ' answered with 'yes there is and it has been entered in EDC since 25NOV2020 with the original terminology entered properly. Please verify all data before entering unnecessary queries ' (Site from DM).	Reagan Reed (b) (4) (b) (4)	23 Dec 2020 16:56:17

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:47:13

[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 time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 22:50:57
User entered 'Skin rash of right breast'	Afifah Ayub (b) (4) (b) (4)	23 Nov 2020 15:55:15

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:47:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:22
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '300'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Nov 2020 15:55:15

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:47:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:22
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'mg (mg)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Nov 2020 15:55:15

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:47:13

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:22
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Nov 2020 15:55:15

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:47:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:22
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'three times daily (TID)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Nov 2020 15:55:15

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:47:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:22
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Nov 2020 15:55:15

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:47:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:22
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Oral (ORAL)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Nov 2020 15:55:15

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:47:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:22
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered empty.	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Nov 2020 15:55:15

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:22
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '17 Nov 2020'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Nov 2020 15:55:15

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:47:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:22
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '0'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Nov 2020 15:55:15

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:47:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:22
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Afifah Ayub (b) (4)	04 Dec 2020 17:40:42
User entered 'Yes (Y)'	(b) (4)	
	Afifah Ayub (b) (4)	23 Nov 2020 15:55:15
	(b) (4)	

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:47:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:22
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered '28 Nov 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	11 Mar 2021 14:31:34
User closed query ' Per DM CLR: Please review the ConMed stop date as it was noted this is after the stop date of the corresponding AE. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 14:12:58
Query ' Per DM CLR: Please review the ConMed stop date as it was noted this is after the stop date of the corresponding AE. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated per source' (Site from DM).	Reagan Reed (b) (4) (b) (4)	19 Jan 2021 22:44:33
User entered '20 Nov 2020' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	19 Jan 2021 22:44:27
User opened query ' Per DM CLR: Please review the ConMed stop date as it was noted this is after the stop date of the corresponding AE. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	16 Jan 2021 02:07:41
User entered '28 Nov 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	04 Dec 2020 17:40:42
User entered empty.	Afifah Ayub (b) (4) (b) (4)	23 Nov 2020 15:55:15

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:47:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:22
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'No (N)'	(b) (4) Afifah Ayub (b) (4) (b) (4)	23 Nov 2020 15:55:15

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:47:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:22
User entered '3'	System	23 Nov 2020 15:55:15

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:47:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:22
User entered '1'	System	23 Nov 2020 15:55:15

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:47:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:22
User entered '804 (804)'	System	23 Nov 2020 15:55:15

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:47:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:29
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Apr 2021 13:45:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 13:45:31
Data point term sent to Coder	System	25 Mar 2021 13:12:09
Coding entries removed.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:11:35
Coding entries removed.	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:11:35
User entered 'Hydrocodone-Acetaminophen (Norco)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:11:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: CODIN [OXYCODONE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Dec 2020 23:33:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Dec 2020 23:33:23
Data point term sent to Coder	System	30 Dec 2020 22:47:46
User entered 'Codine'	Reagan Reed (b) (4)	30 Dec 2020 22:47:31

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:47:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:29
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'No (N)'	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:47:31

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:47:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:29
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Pelvic Pain' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:11:35
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.'	(b) (4), (b) (6)	24 Feb 2021 09:27:12
(Site from DM).		
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.'	Reagan Reed (b) (4)	23 Feb 2021 21:40:39
' answered with 'please see procedure log' (Site from DM).	(b) (4)	
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.'	(b) (4), (b) (6)	05 Feb 2021 07:27:38
(Site from DM).		
User entered 'Hysterectomy'	Reagan Reed (b) (4)	30 Dec 2020 22:47:31
	(b) (4)	

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:47:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:29
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '5-325' reason for change: Data Entry Error	(b) (4)	25 Mar 2021 13:11:35
User entered '30'	Laura Ngansop Djampou (b) (4)	30 Dec 2020 22:47:31
	Reagan Reed (b) (4)	
	(b) (4)	

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:47:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:29
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'mg (mg)'	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:47:31

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:47:13

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:29
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered empty.	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:47:31

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:47:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:29
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'as needed (PRN)'	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:47:31

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:47:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:29
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered empty.	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:47:31

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:47:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:29
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Oral (ORAL)'	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:47:31

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:47:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:29
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered empty.	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:47:31

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:29
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '17 Dec 2020'	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:47:31

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:47:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:29
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '0'	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:47:31

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:47:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:29
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'No (N)'	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:47:31

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:47:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:29
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '19 Dec 2020'	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:47:31

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:47:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:29
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'No (N)'	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:47:31

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:47:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:29
User entered empty.	System	30 Dec 2020 22:47:31

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:47:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:29
User entered empty.	System	30 Dec 2020 22:47:31

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:47:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:29
User entered empty.	System	30 Dec 2020 22:47:31

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:47:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:35
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 13:12:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 13:12:26
Data point term sent to Coder Coding entries removed.	System Laura Ngansop Djampou	25 Mar 2021 13:11:08 25 Mar 2021 13:10:40
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Dec 2020 23:38:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Dec 2020 23:38:22
Data point term sent to Coder User entered 'Ibuprofen'	System Reagan Reed (b) (4)	30 Dec 2020 22:48:48 30 Dec 2020 22:48:06

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:47:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:35
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'No (N)'	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:48:06

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:47:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:35
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	02 Apr 2021 18:10:58
User entered 'Pelvic Pain' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Mar 2021 13:10:40
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.'	(b) (4), (b) (6)	24 Feb 2021 09:27:30
(Site from DM).		
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.'	Reagan Reed (b) (4) (b) (4)	23 Feb 2021 21:41:05
' answered with 'see procedure log ensure that DMCLR checks all data before issuing queries ' (Site from DM).		
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.'	(b) (4), (b) (6)	05 Feb 2021 07:27:57
(Site from DM).		
User entered 'Hysterectomy'	Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:48:06

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:47:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:35
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '600'	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:48:06

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:47:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:35
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'mg (mg)'	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:48:06

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:47:13

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:35
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered empty.	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:48:06

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:47:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:35
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'as needed (PRN)'	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:48:06

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:47:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:35
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered empty.	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:48:06

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:47:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:35
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Oral (ORAL)'	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:48:06

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:47:13

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:35
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered empty.	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:48:06

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:47:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:35
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '17 Dec 2020'	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:48:06

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:47:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:35
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '0'	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:48:06

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:47:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:35
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	25 Mar 2021 13:10:40
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	30 Dec 2020 22:48:06
	Reagan Reed (b) (4)	
	(b) (4)	

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:47:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:35
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '27 Dec 2020' reason for change: Data Entry Error	(b) (4)	25 Mar 2021 13:10:40
User entered empty.	Laura Ngansop Djampou (b) (4)	30 Dec 2020 22:48:06
	(b) (4)	

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:47:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:35
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'No (N)'	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:48:06

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:47:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:35
User entered empty.	System	30 Dec 2020 22:48:06

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:47:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:35
User entered empty.	System	30 Dec 2020 22:48:06

US3212100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:47:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:35
User entered empty.	System	30 Dec 2020 22:48:06

US3212100

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:47:13

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:28:02
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Afifah Ayub (b) (4)	28 Sep 2020 18:23:31
User entered 'No (N)'	(b) (4)	
	Afifah Ayub (b) (4)	10 Aug 2020 15:56:07
	(b) (4)	

US3212100

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:47:13

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
	(b) (4)	
User entered '17 Sep 2020'	Afifah Ayub (b) (4)	28 Sep 2020 18:23:51
	(b) (4)	

US3212100

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:47:13

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'pelvic ultrasound'	(b) (4) Afifah Ayub (b) (4) (b) (4)	28 Sep 2020 18:23:51

US3212100

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:47:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User closed query 'Per DM CLR/Requery: Response noted 'AE record #3'. However, date of this procedure is after the stop date of the corresponding AE and Other Action Taken does not include 'Concomitant Procedure' in AE eCRF. Please reconcile and update as appropriate, otherwise clarify.' (Site from DM). Query 'Per DM CLR/Requery: Response noted 'AE record #3'. However, date of this procedure is after the stop date of the corresponding AE and Other Action Taken does not include 'Concomitant Procedure' in AE eCRF. Please reconcile and update as appropriate, otherwise clarify.' answered with 'initial pelvic ultrasound conducted on 17SEP2020 was for back pain' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 09:59:59
User opened query 'Per DM CLR/Requery: Response noted 'AE record #3'. However, date of this procedure is after the stop date of the corresponding AE and Other Action Taken does not include 'Concomitant Procedure' in AE eCRF. Please reconcile and update as appropriate, otherwise clarify.'	Reagan Reed (b) (4) (b) (4)	04 Mar 2021 16:48:15
User opened query 'Per DM CLR/Requery: Response noted 'AE record #3'. However, date of this procedure is after the stop date of the corresponding AE and Other Action Taken does not include 'Concomitant Procedure' in AE eCRF. Please reconcile and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 07:53:05
User closed query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Adverse Event) as appropriate, otherwise clarify.. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 13:25:23
Query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Adverse Event) as appropriate, otherwise clarify.. ' answered with 'AE record #3' (Site from DM).	Afifah Ayub (b) (4) (b) (4)	05 Oct 2020 17:17:19
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	05 Oct 2020 17:17:06

US3212100

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:47:13

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Adverse Event) as appropriate, otherwise clarify..' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:46:38
User entered 'Other (OTHER)'	Afifah Ayub (b) (4) (b) (4)	28 Sep 2020 18:23:51

US3212100

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:47:13

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered empty; reason for change Data Entry Error	(b) (4) Afifah Ayub (b) (4)	05 Oct 2020 17:17:06
User entered 'back pain'	(b) (4) Afifah Ayub (b) (4)	28 Sep 2020 18:23:51

US3212100

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:47:13

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:58
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '1 Dec 2020'	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:45:43

US3212100

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:47:13

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:58
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Pelvic Ultrasound'	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:45:43

US3212100

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:47:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:58
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Medical History (MH)'	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:45:43

US3212100

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:47:13

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:58
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered empty.	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:45:43

US3212100

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:47:13

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:27:02
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '15 Dec 2020'	(b) (4) Reagan Reed (b) (4) (b) (4)	30 Dec 2020 22:45:58

US3212100

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:47:13

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:27:02
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Total Abdominal Hysterectomy'	(b) (4)	
reason for change: Data Entry Error	Laura Ngansop Djampou	24 Mar 2021 21:36:12
User entered 'Hysterectomy'	(b) (4)	
	Reagan Reed (b) (4)	30 Dec 2020 22:45:58
	(b) (4)	

US3212100

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:47:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:27:02
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'Other (OTHER)' reason for change:	(b) (4)	
Data Entry Error	Jagruti Patel (b) (4)	25 Mar 2021 14:02:58
User entered 'Medical History (MH)'	(b) (4)	
	Reagan Reed (b) (4)	30 Dec 2020 22:45:58
	(b) (4)	

US3212100

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:47:13

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:27:02
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered 'MEDICAL HISTORY ((Leiomyoma of Uterus) AND ADVERSE EVENT (Pelvic pain)' reason for change: Data Entry Error	(b) (4)	
	Jagruti Patel (b) (4)	25 Mar 2021 14:03:59
	(b) (4)	
User entered 'Medical History and Adverse Event' reason for change: Data Entry Error	Jagruti Patel (b) (4)	25 Mar 2021 14:02:58
	(b) (4)	
User entered empty.	Reagan Reed (b) (4)	30 Dec 2020 22:45:58
	(b) (4)	

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'USA-US115-2021-MRNA-1273-P301000001'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

Serious

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'Yes (Y)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'No (N)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'No (N)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'Yes (Y)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'No (N)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'No (N)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'No (N)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:24:10
Un-reviewed for Safety.	System	26 Mar 2021 13:24:06
User entered empty.	System	26 Mar 2021 13:24:06
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'Vicki'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:24:10
Un-reviewed for Safety.	System	26 Mar 2021 13:24:06
User entered empty.	System	26 Mar 2021 13:24:06
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'Miller'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:42:49
User entered 'US'	System	04 Jan 2021 17:12:24

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Mar 2021 13:24:06
User entered '2'	System	03 Feb 2021 16:43:02
User entered '1'	System	04 Jan 2021 17:12:24

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'USA-US115-2021-MRNA-1273-P301000001'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

Serious

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'Yes (Y)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'No (N)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'No (N)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'Yes (Y)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'No (N)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'No (N)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'No (N)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	26 Mar 2021 13:24:10
Un-reviewed for Safety.	System	26 Mar 2021 13:24:06
User entered empty.	System	26 Mar 2021 13:24:06
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'Vicki'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:24:10
Un-reviewed for Safety.	System	26 Mar 2021 13:24:06
User entered empty.	System	26 Mar 2021 13:24:06
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'Miller'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:42:49
User entered 'US'	System	04 Jan 2021 17:12:24

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Mar 2021 13:24:06
User entered '2'	System	03 Feb 2021 16:43:02
User entered '1'	System	04 Jan 2021 17:12:24

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:47:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '04/Jan/2021 17:12'	(b) (4) System	04 Jan 2021 17:12:24

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:47:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:42:49
User entered 'I'	(b) (4), (b) (6)	04 Jan 2021 17:12:24

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'USA-US115-2021-MRNA-1273-P301000001'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

Serious

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'Yes (Y)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'No (N)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'No (N)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'Yes (Y)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'No (N)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'No (N)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'No (N)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:24:10
Un-reviewed for Safety.	System	26 Mar 2021 13:24:06
User entered empty.	System	26 Mar 2021 13:24:06
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'Vicki'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:24:10
Un-reviewed for Safety.	System	26 Mar 2021 13:24:06
User entered empty.	System	26 Mar 2021 13:24:06
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'Miller'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:42:49
User entered 'US'	System	04 Jan 2021 17:12:24

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Mar 2021 13:24:06
User entered '2'	System	03 Feb 2021 16:43:02
User entered '1'	System	04 Jan 2021 17:12:24

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:47:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '03/Feb/2021 11:43'	(b) (4) System	03 Feb 2021 16:43:02

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:47:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	26 Mar 2021 13:24:10
User entered 'I'	(b) (4), (b) (6)	03 Feb 2021 16:43:02

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'USA-US115-2021-MRNA-1273-P301000001'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

Serious

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'Yes (Y)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'No (N)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'No (N)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'Yes (Y)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'No (N)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'No (N)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'No (N)'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:24:10
Un-reviewed for Safety.	System	26 Mar 2021 13:24:06
User entered empty.	System	26 Mar 2021 13:24:06
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'Vicki'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:24:10
Un-reviewed for Safety.	System	26 Mar 2021 13:24:06
User entered empty.	System	26 Mar 2021 13:24:06
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 17:12:17
User entered 'Miller'	System	04 Jan 2021 17:11:55

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:42:49
User entered 'US'	System	04 Jan 2021 17:12:24

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:47:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Mar 2021 13:24:06
User entered '2'	System	03 Feb 2021 16:43:02
User entered '1'	System	04 Jan 2021 17:12:24

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:47:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
User entered '26/Mar/2021 09:24'	(b) (4) System	26 Mar 2021 13:24:06

US3212100

Folder: SAE USA-US115-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:47:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	02 Apr 2021 18:10:58
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	26 Mar 2021 13:24:10
User entered 'I'	(b) (4), (b) (6)	26 Mar 2021 13:24:06